

EPA Reg. No. 87655-1
Volume 1

ISB'S Front-end PRIA Completeness Screen

Draft 3; 10/25/07

EPA Receipt Date: <i>5/28/10</i>		EPA Reg. Number: <i>87655-R</i>		
	Check List Item	Yes	No	N/A
1	Has the PRIA Fee been Paid ; is a copy of the check or Pay.gov receipt included in the Submission Package?	✓		
2	Is an Application Form (EPA Form 8570-1) Included in the Submission Package, is it completely filled out and signed including package type?	✓		
3	Is a Confidential Statement of Formula (EPA Form 8570-29) Included in the Submission Package, is it completely filled out and signed (boxes 1-21)?	✓		
4	Is a Formulator's Exemption Statement (EPA Form 8570-27) Included in the Submission Package?		✓	
5	Is a Certification with Respect to Citation of Data (EPA Form 8570-34) Included in the Submission Package?	✓		
6	Is a Data Matrix (EPA Form 8570-35) Included in the Submission Package?	✓		
7	Is a Label Included in the Submission Package?	✓		
8	Are Data Included in the Submission Package?	✓		
9	Is the Submission an Amendment?		✓	

April 14, 2011

Document Processing Desk (APPL)
Office of Pesticide Programs (P7504C)
Environmental Protection Agency
Room S-4900, One Potomac Yard (South Building)
2777 S. Crystal Drive
Arlington, VA 22202

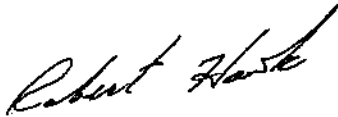
Attn: Kathryn Montague (PM 23), Registration Division

Dear Ms. Montague:

Subject: Fomesafen Technical (87655-1): Final Label

Thank you for the Notice of Pesticide Registration of April 8, 2011. Please find enclosed Form 8570-1 and one copy of the final label.

Sincerely,



Robert Hawk, Agent
Orion Fomes, LLC
rhawk@solasd.com
tel. 928-342-3489



United States
Environmental Protection Agency
Washington, DC 20460

☒ Registration
☐ Amendment
☐ Other

OPP Identifier Number

Application for Pesticide - Section I

1. Company/Product Number 87655-1	2. EPA Product Manager K. Montague	3. Proposed Classification <input type="checkbox"/> None <input checked="" type="checkbox"/> Restricted
4. Company/Product (Name) Fomesafen Technical	PM# 23	
5. Name and Address of Applicant (Include ZIP Code) Orion Fomes, LLC P. O. Box 21720 Mesa, AZ 85277 <input type="checkbox"/> Check if this is a new address	6. Expedited Review. In accordance with FIFRA Section 3(c)(3) [b](ii), my product is similar or identical in composition and labeling to: EPA Reg. No. 82633-5 Product Name Sharda Fomesafen Technical Herbicide	

Section - II

<input type="checkbox"/> Amendment - Explain below.	<input checked="" type="checkbox"/> Final printed labels in response to Agency letter dated Apr. 8, 2011
<input type="checkbox"/> Resubmission in response to Agency letter dated _____	<input type="checkbox"/> "Me Too" Application.
<input type="checkbox"/> Notification - Explain below.	<input type="checkbox"/> Other - Explain below.

Explanation: Use additional page(s) if necessary. (For section I and Section II.)

Submission of final label.

Section - III

1. Material This Product Will Be Packaged In:				2. Type of Container	
Child-Resistant Packaging <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	Unit Packaging <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	Water Soluble Packaging <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No		<input type="checkbox"/> Metal	<input checked="" type="checkbox"/> Plastic
* Certification must be submitted		If "Yes" Unit Packaging wgt.	No. per container	If "Yes" Package wgt	No. per container
3. Location of Net Contents Information <input type="checkbox"/> Label <input checked="" type="checkbox"/> Container		4. Size(s) Retail Container 40 kg (not retail)		5. Location of Label Directions <input type="checkbox"/> On Label <input checked="" type="checkbox"/> On Labeling accompanying product	
6. Manner in Which Label is Affixed to Product <input type="checkbox"/> Lithograph <input checked="" type="checkbox"/> Paper glued <input type="checkbox"/> Stenciled				<input type="checkbox"/> Other _____	

Section - IV

1. Contact Point (Complete items directly below for identification of individual to be contacted, if necessary, to process this application.)					
Name Robert Hawk		Title Agent		Telephone No. (Include Area Code) 928-342-3489	
Certification I certify that the statements I have made on this form and all attachments thereto are true, accurate and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law.					6. Date Application Received (Stamped)
2. Signature 		3. Title Agent			
4. Typed Name Robert Hawk		5. Date Apr. 14, 2011			

Orion Fomes final label April 14, 2011

FOMESAFEN TECHNICAL

FOR FORMULATING USE ONLY

ACTIVE INGREDIENT

Fomesafen [5-[2-chloro-4-trifluoromethyl)phenoxy]-N-(methylsulfonyl)-2-nitrobenzamide].....98.0%

OTHER INGREDIENTS:.....2.0%**TOTAL**..... 100.0%

KEEP OUT OF REACH OF CHILDREN

DANGER/PELIGRO

Si usted no entiende la etiqueta, busque a alguien para que se la explique a usted en detalle.
(If you do not understand the label, find someone to explain it to you in detail.)

See Additional Precautionary Statements and Directions for Use on label.

FIRST AID

IF IN EYES	<ul style="list-style-type: none"> • Hold eye open and rinse slowly and gently with water for 15-20 minutes. • Remove contact lenses, if present, after the first 5 minutes, then continue rinsing eye. • Call a poison control center or doctor for treatment advice.
IF SWALLOWED	<ul style="list-style-type: none"> • Call a poison control center or doctor immediately for treatment advice. • Have person sip a glass of water if able to swallow. • Do not induce vomiting unless told to do so by a poison control center or doctor. • Do not give anything by mouth to an unconscious person.
IF ON SKIN OR CLOTHING	<ul style="list-style-type: none"> • Take off contaminated clothing. • Rinse skin immediately with plenty of water for 15-20 minutes. • Call a poison control center or doctor for treatment advice.
IF INHALED	<ul style="list-style-type: none"> • Move person to fresh air. • If person is not breathing, call 911 or an ambulance, then give artificial respiration, preferably by mouth-to-mouth if possible. • Call a poison control center or doctor for further treatment advice.

EMERGENCY NUMBERS

For **MEDICAL** Emergencies 24 Hours a Day Call a Poison Control Center at 1-800-222-1222.
For **CHEMICAL** Emergency Assistance (Spill, Fire or Accident) Call ChemTrec at 1-800-424-9300
Have the product container or label with you when calling a Poison Control Center or doctor or going for treatment.

NOTE TO PHYSICIAN

Probable mucosal damage may contraindicate the use of gastric lavage.

Orion Fomes, LLC
P.O. Box 21720
Mesa, AZ 85277

EPA Reg. No. 87655-1
EPA Est. No. xxxxxxxx
Net Contents: 30 kg

Tel. 480-218-4289

Terrestrial Food Use: Soybeans

Uses for which the USEPA has accepted the required data and/or citations of data that the formulator has submitted in support of registration, and uses for experimental purposes that are in compliance with USEPA requirements.

STORAGE AND DISPOSAL

Do not contaminate water, food, or feed by storage, disposal, or cleaning of equipment.

PESTICIDE STORAGE: Store above 32°F in original container only. Keep container closed when not in use. Do not store near food or feed. In case of spill on floor or paved surfaces, sweep up and remove to chemical waste area.

PESTICIDE DISPOSAL: Pesticide wastes are acutely toxic. Improper disposal of excess pesticide, spray mixture, or rinsate is a violation of Federal law. If these wastes cannot be disposed of by use according to label instructions, contact your State Pesticide or Environmental Control Agency or the Hazardous Waste representative at the nearest EPA Regional Office for guidance.

CONTAINER DISPOSAL: Nonrefillable container. Do not reuse empty container.

Triple rinse as follows: Empty the remaining contents into application equipment or a mix tank. Fill the container ¼ full with water. Replace and tighten closures. Tip container on its side and roll it back and forth, ensuring at least one complete revolution, for 30 seconds. Stand the container on its end and tip it back and forth several times. Turn the container over onto its other end and tip it back and forth several times. Empty the rinsate into the application equipment or a mix tank to store rinsate for later use or disposal. Drain for 10 seconds after the flow begins to drip. Repeat this procedure two more times.

Pressure rinse as follows: Empty the remaining contents into application equipment or a mix tank and continue to drain for 10 seconds after the flow begins to drip. Hold the container upside down over mix tank or collect rinsate for later use or disposal. Insert pressure rinsing nozzle in the side of the container and rinse at about 40 PSI for at least 30 seconds. Drain for 10 seconds after the flow begins to drip. Then offer for recycling if available or puncture and dispose of in a sanitary landfill, or by incineration, or, if allowed by state and local authorities, by burning. If burned, stay out of smoke.

DISCLAIMER OF WARRANTIES: TO THE EXTENT CONSISTENT WITH APPLICABLE LAW, ORION FOMES LLC MAKES NO OTHER WARRANTIES, EXPRESS OR IMPLIED, OF MERCHANTABILITY OR OF FITNESS FOR A PARTICULAR PURPOSE OR OTHERWISE, THAT EXTEND BEYOND THE STATEMENTS MADE ON THIS LABEL. No agent of Orion Fomes LLC is authorized to make any warranties beyond those contained herein or to modify the warranties contained herein.

TO THE EXTENT CONSISTENT WITH APPLICABLE LAW, ORION FOMES LLC DISCLAIMS ANY LIABILITY WHATSOEVER FOR SPECIAL, INCIDENTAL OR CONSEQUENTIAL DAMAGES RESULTING FROM THE USE OR HANDLING OF THIS PRODUCT.

LIMITATIONS OF LIABILITY: TO THE EXTENT CONSISTENT WITH APPLICABLE LAW, THE EXCLUSIVE REMEDY OF THE USER OR BUYER FOR ANY AND ALL LOSSES, INJURIES OR DAMAGES RESULTING FROM THE USE OR HANDLING OF THIS PRODUCT, WHETHER IN CONTRACT, WARRANTY, TORT, NEGLIGENCE, STRICT LIABILITY OR OTHERWISE, SHALL NOT EXCEED THE PURCHASE PRICE PAID, OR AT ORION FOMES LLC'S ELECTION, THE REPLACEMENT OF PRODUCT.

Material to be added to an e-Jacket/Jacket

Reg. No. 87655-1

Description: NEW PRODUCT
DESIGN # 434408

1. ☐ Placement within the e-Jacket/jacket:
- ☐ Default: (chronological, top = newest)
 - ☐ File Location: (PDF page number, i.e., "before page 45")
-
-

2. ☐ Send to Data Extraction contractors this material:

- ☒ Newly stamped accepted label
- ☐ Notification
- ☐ New CSF
- ☐ Other: _____

3. Attach this coversheet to the top of the material or jacket. It must be well organized and clipped together, NOT STAPLED. Then give the material with this coversheet to staff in the Information Services Center (Room S-4900).

Reviewer's Name: Michael Walsh

Phone: 308-2972 Division: RD/HB

Date: 3/31/11

Created August 27, 2008



**ENVIRONMENTAL PROTECTION
AGENCY**

Office of Pesticide Programs
Registration Division (7505P)
Ariel Rios Building
1200 Pennsylvania Ave., NW
Washington, D.C. 20460

Reg. Number:

87655-1

Date of Issuance:

11/11/11

NOTICE OF PESTICIDE:

☒ Registration

☐ Reregistration

(under FIFRA, as amended)

Term of Issuance:

Conditional

Name of Pesticide Product:

Fomesafen Technical

Name and Address of Registrant (include ZIP Code):

Orion Fomes, LLC
P.O. Box 21720
Mesa, AZ 85277

Note: Changes in labeling differing in substance from that accepted in connection with this registration must be submitted to and accepted by the Registration Division prior to use of the label in commerce. In any correspondence on this product always refer to the above EPA registration number.

On the basis of information furnished by the registrant, the above named pesticide is hereby registered/reregistered under the Federal Insecticide, Fungicide and Rodenticide Act. Registration is in no way to be construed as an endorsement or recommendation of this product by the Agency. In order to protect health and the environment, the Administrator, on his motion, may at any time suspend or cancel the registration of a pesticide in accordance with the Act. The acceptance of any name in connection with the registration of a product under this Act is not to be construed as giving the registrant a right to exclusive use of the name or to its use if it has been covered by others.

This product is conditionally registered in accordance with FIFRA sec. 3(c)(7)(A) provided that you:

- 1) Submit and/or cite all data required for registration/reregistration review of your product when the Agency requires all registrants of similar products to submit data. If required, failure to submit acceptable data to fulfill these requirements may result in registration cancellation in accordance with FIFRA section 6(e).
- 2) Add the phrase "EPA Reg. No. 87655-1" to the labeling and assure that the EPA Establishment Number and Net Contents are also on the label.
- 3) Generate one-year storage stability (830.6317) and corrosion characteristics (830.6320) data on the product. The observations should be made at 0, 3, 6, 9, and 12 month intervals. The results must be submitted to the Agency in electronic and hard copy format within 15 months of the date on this notice.
- 4) On page 1 under the product name, please correct the typographical error in the Spanish signal word that now reads "DANGER/PELOGRO". Per the Label Review Manual, the signal word must read "DANGER / PELIGRO".
- 5) NOTE: While not required, it may be helpful to product users if the emergency telephone numbers in the First Aid box are identified as such. If you so choose, you may add a header identifying the telephone numbers listed as Emergency Numbers. The header below or similar language is acceptable.

EMERGENCY NUMBERS

"For MEDICAL Emergencies 24 hours a day....."

SEE NEXT PAGE FOR ADDITIONAL COMMENTS

Signature of Approving Official:
Kathryn V. Montague
Product Manager 23
Herbicide Branch
Registration Division (7505P)

Date:

6) Per the Label Review Manual, the following edits addressing a missing sentence in the triple rinse section and adding instructions regarding the ultimate disposition of the container must be added to the label. Add the text below in bold to the product label.

CONTAINER DISPOSAL: Nonrefillable container. Do not reuse empty container.

Triple rinse as follows: Empty the remaining contents into application equipment or a mix tank. Fill the container $\frac{1}{4}$ full with water. Replace and tighten closures. Tip container on its side and roll it back and forth, ensuring at least one complete revolution, for 30 seconds. Stand the container on its end and tip it back and forth several times. **Turn the container over onto its other end and tip it back and forth several times.** Empty the rinsate into application equipment or a mix tank or store rinsate for later use or disposal. Repeat this procedure two more times.

Pressure rinse as follows: Empty the remaining contents into application equipment or a mix tank and continue to drain for 10 seconds after the flow begins to drip. Hold the container upside down over application equipment or mix tank or collect rinsate for later use or disposal. Insert pressure rinsing nozzle in the side of the container, and rinse at about 40 PSI for at least 30 seconds. Drain for 10 seconds after the flow begins to drip. **Then offer for recycling if available or puncture and dispose of in a sanitary landfill, or by incineration, or, if allowed by state and local authorities, by burning. If burned, stay out of smoke."**

7) NOTE: While no additional data is being requested at this time, marketing claims made on the pesticide label must be substantiated by data maintained in your files. If data supporting marketing claims made on the product label is not available then those claims must be removed.

8) NOTE: Should you wish to add/retain a reference to the company's website on your label, then please be aware that the website becomes labeling under the Federal Insecticide Fungicide and Rodenticide Act and is subject to review by the Agency. If the website is false or misleading, the product would be misbranded and unlawful to sell or distribute under FIFRA section 12(a)(1)(E). 40 CFR 156.10(a)(5) list examples of statements EPA may consider false or misleading. In addition, regardless of whether a website is referenced on your product's label, claims made on the website may not substantially differ from those claims approved through the registration process. Therefore, should the Agency find or if it is brought to our attention that a website contains false or misleading statements or claims substantially differing from the EPA approved registration, the website will be referred to the EPA's Office of Enforcement and Compliance.

9) Submit one (1) copy of the revised final printed label before the product is released for shipment.

If these conditions are not complied with, the registration will be subject to cancellation in accordance with FIFRA sec. 6(e). Your release for shipment of the product constitutes acceptance of these conditions. A stamped copy of the label is enclosed for your records.

draft Orion Fomes Fomesafen label May 25, 2010

FOMESAFEN TECHNICAL

FOR FORMULATING USE ONLY

ACTIVE INGREDIENT

Fomesafen [5-[2-chloro-4-trifluoromethylphenoxy]-N-(methylsulfonyl)-2-nitrobenzamide].....98.0%

OTHER INGREDIENTS:.....2.0%**TOTAL**..... 100.0%

KEEP OUT OF REACH OF CHILDREN

DANGER/PELOGRO

Si usted no entiende la etiqueta, busque a alguien para que se la explique a usted en detalle.
(If you do not understand the label, find someone to explain it to you in detail.)

See Additional Precautionary Statements and Directions for Use on label.

FIRST AID

IF IN EYES	<ul style="list-style-type: none"> • Hold eye open and rinse slowly and gently with water for 15-20 minutes. • Remove contact lenses, if present, after the first 5 minutes, then continue rinsing eye. • Call a poison control center or doctor for treatment advice.
IF SWALLOWED	<ul style="list-style-type: none"> • Call a poison control center or doctor immediately for treatment advice. • Have person sip a glass of water if able to swallow. • Do not induce vomiting unless told to do so by a poison control center or doctor. • Do not give anything by mouth to an unconscious person.
IF ON SKIN OR CLOTHING	<ul style="list-style-type: none"> • Take off contaminated clothing. • Rinse skin immediately with plenty of water for 15-20 minutes. • Call a poison control center or doctor for treatment advice.
IF INHALED	<ul style="list-style-type: none"> • Move person to fresh air. • If person is not breathing, call 911 or an ambulance, then give artificial respiration, preferably by mouth-to-mouth if possible. • Call a poison control center or doctor for further treatment advice.

For **MEDICAL** Emergencies 24 Hours a Day Call a Poison Control Center at 1-800-222-1222.For **CHEMICAL** Emergency Assistance (Spill, Fire or Accident) Call ChemTrec at 1-800-424-9300

Have the product container or label with you when calling a Poison Control Center or doctor or going for treatment.

NOTE TO PHYSICIAN

Probable mucosal damage may contraindicate the use of gastric lavage.

Orion Fomes, LLC**P.O. Box 21720****Mesa, AZ 85277****ACCEPTED****with COMMENTS****In EPA Letter Dated: Tel. 480-218-4289****EPA Reg. No. 87655-x****EPA Est. No. XXXXXXXX****Net Contents: 30 kg**

Under the Federal Insecticide,
Fungicide, and Rodenticide Act
as amended, for the pesticide
registered under EPA Reg. No.

87655-x-1

PRECAUTIONARY STATEMENTS

HAZARDS TO HUMANS AND DOMESTIC ANIMALS

CORROSIVE. CAUSES IRREVERSIBLE EYE DAMAGE. DUE TO CORROSIVE NATURE, MAY BE HARMFUL OR FATAL IF SWALLOWED. HARMFUL IF INHALED OR ABSORBED THROUGH SKIN. Do not get in eyes, on skin or on clothing. Avoid breathing vapor.

PERSONAL PROTECTIVE EQUIPMENT (PPE)

Manufacturers and other handlers must wear:

- ◊ Coveralls
- ◊ Waterproof gloves
- ◊ Shoes plus socks
- ◊ Protective eyewear

Discard clothing and other absorbent materials that have been heavily contaminated with this technical material. Do not reuse them.

USER SAFETY RECOMMENDATIONS

Users should:

- ◊ Wash thoroughly with soap and water after handling and before eating, drinking, chewing gum, using tobacco or using the toilet.
- ◊ Remove clothing immediately if pesticide gets inside. Then wash thoroughly and put on clean clothing.
- ◊ Remove PPE immediately after handling this product. Wash the outside of gloves before removing. As soon as possible, wash thoroughly and change into clean clothing.

ENVIRONMENTAL HAZARDS

Do not discharge effluent containing this product into lakes, streams, ponds, estuaries, oceans or other waters unless in accordance with the requirements of a National Pollutant Discharge Elimination System (NPDES) permit and the permitting authority has been notified in writing prior to discharge. Do not discharge effluent containing this product to sewer systems without previously notifying the local sewage treatment plant authority. For guidance contact your State Water Board or Regional Office of the EPA.

DIRECTIONS FOR USE

It is a violation of federal law to use this product in a manner inconsistent with its labeling.

Formulators using this product are responsible for obtaining EPA registration for their formulated products.

Fomesafen Technical is intended solely for the formulation into herbicide products intended for the following uses:

Terrestrial Food Use: Soybeans

Uses for which the USEPA has accepted the required data and/or citations of data that the formulator has submitted in support of registration, and uses for experimental purposes that are in compliance with USEPA requirements.

STORAGE AND DISPOSAL

Do not contaminate water, food, or feed by storage, disposal, or cleaning of equipment.

PESTICIDE STORAGE: Store above 32°F in original container only. Keep container closed when not in use. Do not store near food or feed. In case of spill on floor or paved surfaces, sweep up and remove to chemical waste area.

PESTICIDE DISPOSAL: Pesticide wastes are acutely toxic. Improper disposal of excess pesticide, spray mixture, or rinsate is a violation of Federal law. If these wastes cannot be disposed of by use according to label instructions, contact your State Pesticide or Environmental Control Agency or the Hazardous Waste representative at the nearest EPA Regional Office for guidance.

CONTAINER DISPOSAL: Nonrefillable container. Do not reuse empty container.

Triple rinse as follows: Empty the remaining contents into application equipment or a mix tank. Fill the container ¼ full with water. Replace and tighten closures. Tip container on its side and roll it back and forth, ensuring at least one complete revolution, for 30 seconds. Stand the container on its end and tip it back and forth several times. Empty the rinsate into the application equipment or a mix tank to store rinsate for later use or disposal. Drain for 10 seconds after the flow begins to drip. Repeat this procedure two more times.

Pressure rinse as follows: Empty the remaining contents into application or a mix tank. Hold container upside down over mix tank or collect rinsate for later use or disposal. Insert pressure rinsing nozzle in the side of the container and rinse at about 40 PSI for at least 30 seconds. Drain for 10 seconds after the flow begins to drip.

DISCLAIMER OF WARRANTIES: TO THE EXTENT CONSISTENT WITH APPLICABLE LAW, ORION FOMES LLC MAKES NO OTHER WARRANTIES, EXPRESS OR IMPLIED, OF MERCHANTABILITY OR OF FITNESS FOR A PARTICULAR PURPOSE OR OTHERWISE, THAT EXTEND BEYOND THE STATEMENTS MADE ON THIS LABEL. No agent of Orion Fomes LLC is authorized to make any warranties beyond those contained herein or to modify the warranties contained herein.

TO THE EXTENT CONSISTENT WITH APPLICABLE LAW, ORION FOMES LLC DISCLAIMS ANY LIABILITY WHATSOEVER FOR SPECIAL, INCIDENTAL OR CONSEQUENTIAL DAMAGES RESULTING FROM THE USE OR HANDLING OF THIS PRODUCT.

LIMITATIONS OF LIABILITY: TO THE EXTENT CONSISTENT WITH APPLICABLE LAW, THE EXCLUSIVE REMEDY OF THE USER OR BUYER FOR ANY AND ALL LOSSES, INJURIES OR DAMAGES RESULTING FROM THE USE OR HANDLING OF THIS PRODUCT, WHETHER IN CONTRACT, WARRANTY, TORT, NEGLIGENCE, STRICT LIABILITY OR OTHERWISE, SHALL NOT EXCEED THE PURCHASE PRICE PAID, OR AT ORION FOMES LLC'S ELECTION, THE REPLACEMENT OF PRODUCT.

PRIA DUE DATE: 4/3/11

87655-R



Note to: File

From: Michael Walsh, RD/Herbicide Branch, Tel: 308-2972

Re: New Product Registration, R310

Product Name: Fomesafen Technical

Active Ingredients: Fomesafen at 98.0%

EPA Registration Number: 87655-1 (-R)

Submission Dates: May 25, 2010

Decision Number: 434408

Action

- Registration of new technical product (soybean).
- Cited Product - The registrant's application cited 82633-5 as a similar product.

Acute Toxicology Reviews (B. Backus, November 16, 2010)

- The review determined that this new product is similar to the cited product (82633-5).
- The product must bear the same Precautionary Statements and First Aid information as the cited product. The review stated that "The labels are adequately similar."

TRB Chemistry Reviews (S. Mathur, November 9, 2010 and March 10, 2011)

- The review determined that this new product is similar to the cited product (82633-5) from a chemistry perspective.
- Group A & B data are acceptable, with the exception of Storage Stability and Corrosion Characteristics data required within 15 months of the date on the Notice of Registration.
- The revised basic CSF dated November 11, 2010 is acceptable.
- HED determined that there is a low amount of impurity in the formulation, and that it is unlikely that the impurity would have an appreciable effect on the toxicity.

Label Review

- The TRB Acute Toxicology Review indicated that the precautionary and First Aid statements must be the same as the cited product, and that the proposed product label is adequately similar.
- First Aid – For the purposes of clarity, it would be helpful if the registrant added a header identifying the emergency telephone numbers. See comment #5.
- Cited Product – The label for this product is almost identical to the cited product (82633-5) label approved at registration on January 23, 2009.
- Container Handling – Minor edits required.

Date: March 10, 2011

SUBJECT: Product Chemistry Review of Fomesafen Technical

FROM: Shyam B. Mathur, PhD
Product Chemistry Team Leader
Technical Review Branch/RD (7505C)

S. Mathur
3/10/11

TO: Michael Walsh / Kathryn Montague, RM 23
Herbicide Branch / RD (7505C)

J. J. [Signature]
3/14/11

DP BARCODE: D387488
DECISION No.: 434408
File Symbol No.: 87655-R(a)
PRODUCT: Fomesafen Technical TGA/MUP
PCC: 123802
REGISTRANT: Orion Fomes LLC
USE: Herbicide
FOOD USE: Yes

INTRODUCTION:

The product chemistry data for the proposed fomesafen technical were reviewed previously by TRB (see the product chemistry review under DP379979; MRID No. 481094-01 through 481094-03; dated 11-09-10). It was determined that there was present a new impurity in the proposed active ingredient fomesafen technical (99.49%). This new impurity was not found in the cited product (Reg. No. 82633-5). Consequently it was recommended to the RM that the impurity should be referred to HED to evaluate its toxic characteristics, before the TRB can make similarity decision. HED evaluated the toxic characteristics of the impurity in question and routed the results to TRB in order to determine the substantial similarity of the proposed product and the cited product with Reg. No. 82633-5.

SUMMARY OF FINDINGS & CONCLUSIONS

TRB has evaluated the results of the HED determination and has concluded that:

The proposed product with File Symbol No. 87655-R is substantially similar to the registered product with Reg. No. 82633-5 from the product chemistry point of view. This conclusion is based on the HED evaluation of the toxicology characteristics of the new impurity. The HED's conclusions are given below.

Based on a review of the toxicity data for the parent compound, and a structure-activity relationship analysis (SAR) of the parent and the impurities, HED does not believe that the new TGA would have a different toxicity profile than the currently-registered TGA. Considering the level of the new impurity that would be present, HED has no further concerns.

In review of the toxicity for the identified impurity, a qualitative toxicity prediction tool (DEREK) was used to screen for potential hazards not included in the parent compound. As a positive control, the DREK model was run for the parent fomesafen. Based on the DEREK analysis, plausible carcinogenicity and hepatotoxicity alerts were reported for the parent and the impurity. These alerts are consistent with the effects noted in the toxicity data base. Given the structural similarity to the parent and the relatively low amount of the impurity in the formulation, it is unlikely that the impurity would have an appreciable effect on the toxicity.

HED review is attached in the Confidential Appendix.

CONFIDENTIAL APPENDIX



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

OFFICE OF
CHEMICAL SAFETY AND
POLLUTION PREVENTION

MEMORANDUM

Date: March 2, 2011

Subject: EPA Reg. No. 87655-R. Fomesafen. Impurities Discussion for New Formulation.

PC Code: 123802
Decision No.: 434408
Petition No.: N/A
Risk Assessment Type: N/A
TXR No.: N/A
MRID No.: N/A

DP Barcode: D384968
Registration No.: 87655-R
Regulatory Action: New Registration
Case No.: 7211
CAS No.: 72178-02-0
40 CFR: 180.433

From: Christine Olinger, Chemist
Risk Assessment Branch VII
Health Effects Division (7509P)

Handwritten signature of Christine Olinger.

Through: George Kramer Ph.D., Chemist
Health Effects Division (7509P)

Handwritten signature of George Kramer.

And

Michael S. Metzger, Chief
Risk Assessment Branch VII
Health Effects Division (7509P)

Handwritten signature of Michael S. Metzger.

To: Michael Walsh/Kathryn Montague
Herbicide Branch
Registration Division (7505P)

I. Action Requested

Sharda has proposed registration of a technical grade (TGAI) product of fomesafen that has a different impurity profile from the currently-registered TGAI. The Registration Division (RD) has requested HED comment on one new impurity and its potential effects on the toxicity of the TGAI.

CONFIDENTIAL APPENDIX

II. HED Conclusions

Based on a review of the toxicity data for the parent compound, and a structure-activity relationship analysis (SAR) of the parent and the impurities, HED does not believe that the new TGAI would have a different toxicity profile than the currently-registered TGAI. Considering the level of the new impurity that would be present, HED has no further concerns. A detailed discussion of the toxicity and analysis may be found in the Confidential Appendix to this memorandum.

Attachments:
Confidential Appendix



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

OFFICE OF
CHEMICAL SAFETY AND
POLLUTION PREVENTION

MEMORANDUM

Date: March 2, 2011

Subject: EPA Reg. No. 87655-R. Fomesafen. Impurities Discussion for New Formulation.

PC Code: 123802

Decision No.: 434408

Petition No.: N/A

Risk Assessment Type: N/A

TXR No.: N/A

MRID No.: N/A

DP Barcode: D384968

Registration No.: 87655-R

Regulatory Action: New Registration

Case No.: 7211

CAS No.: 72178-02-0

40 CFR: 180.433

From: Christine Olinger, Chemist
Risk Assessment Branch VII
Health Effects Division (7509P)

Through: George Kramer Ph.D., Chemist
Health Effects Division (7509P)

And

Michael S. Metzger, Chief
Risk Assessment Branch VII
Health Effects Division (7509P)

To: Michael Walsh/Kathryn Montague
Herbicide Branch
Registration Division (7505P)

I. Action Requested

Sharda has proposed registration of a technical grade (TGAI) product of fomesafen that has a different impurity profile from the currently-registered TGAI. The Registration Division (RD) has requested HED comment on one new impurity and its potential effects on the toxicity of the TGAI.

II. HED Conclusions

Based on a review of the toxicity data for the parent compound, and a structure-activity relationship analysis (SAR) of the parent and the impurities, HED does not believe that the new TGAI would have a different toxicity profile than the currently-registered TGAI. Considering the level of the new impurity that would be present, HED has no further concerns. A detailed discussion of the toxicity and analysis may be found in the Confidential Appendix to this memorandum.

Attachments:
Confidential Appendix

Impurity Description

The Registration Division inquired about an impurity in the proposed confidential statement of formula for EPA Reg. No. 87655-R at an upper certified limit of [REDACTED]. The chemical structures of the parent compound and the impurity may be found in Table 1 below.

Table 1. Fomesafen Nomenclature.	
Chemical structure	
Common name	Fomesafen
CAS Name	5-(2-Chloro-4-(trifluoromethyl)phenoxy)-N-(methylsulfonyl)-2-nitrobenzamide
CAS registry number	72178-02-0

Hazard Characterization

Reference: A. LaMay, DP Barcode D373600, 10/12/10

The toxicological database for fomesafen is considered complete and adequate for the purposes of this risk assessment. Fomesafen has a low order of acute toxicity by the oral route of exposure (Toxicity Category III), is severely irritating to the eye and is moderately irritating to the skin. In the subchronic and chronic toxicity study in rats and mice, food consumption or food efficiency, body weight/body-weight gain and histopathological changes in the liver were the parameters that were most often affected. In addition, dogs and mice also showed hematological changes (e.g., decreased erythrocyte count, hemoglobin, or hematocrit). Carcinogenicity was not observed in the rat chronic toxicity/carcinogenicity study. Liver tumors were produced in the mouse carcinogenicity study; however, HED's Cancer Assessment Review Committee (CARC) determined that fomesafen should be classified as "Not Likely to be Carcinogenic to Humans". This decision was based on the weight-of-evidence which supports activation of peroxisome proliferator-activated receptor alpha (PPAR α) as the mode of action for

fomesafen-induced hepatocarcinogenesis in mice. Fomesafen was not considered to be mutagenic, nor did this chemical produce neurotoxic effects. No quantitative or qualitative evidence of increased susceptibility was seen following in utero exposure to rats or rabbits in developmental studies or in the reproduction study.

HED Conclusions

In review of the toxicity for the identified impurity, a qualitative toxicity prediction tool (DEREK) was used to screen for potential hazards not included in the parent compound. As a positive control, the DEREK model was run for the parent fomesafen. Based on the DEREK analysis, plausible carcinogenicity and hepatotoxicity alerts were reported for the parent and the impurity. These alerts are consistent with the effects noted in the toxicity database. Given the structural similarity to the parent and the relatively low amount of the impurity in the formulation, it is unlikely that the impurity would have an appreciable effect on the toxicity.

BARCODE: D379979; Reg. No./FILE SYMBOL No.: 87655-R; PRODUCT: Fomesafen Technical

CONFIDENTIAL APPENDIX

Manufacturing process information may be entitled to confidential treatment

Name of the new impurity

[REDACTED]

BARCODE: D379979; Reg. No. /FILE SYMBOL No.: 87655-R; PRODUCT: Fomesafen Technical

CONFIDENTIAL APPENDIX

Chemical	Fomesafen	Registration No.	87655-R	DP Barcode	D379979
CB Number	?	Product Type	Herbicide	Test Substance	Fomesafen Technical TGAI/MUP

Group A-GLNS 830.1550, 830.1600, 830.1620, 830.1650, 830.1670, 830.1700, 830.1750, & 830.1800: Composition (CSF), Impurities, Preliminary analysis, and Analytical Methods

Compound/Component			Nominal Concentration (% w/w)	Lower Certified limit concentration (% w/w)	Upper Certified limit concentration (% w/w)	Preliminary Analysis Mean \pm s. d. (% w/w)
No	Name	Type				
	Fomesafen CAS No. 72178-02-0	AI	98.0	95.1	100.0	99.49 \pm 0.25
	Impurities					

Name of the new impurity

Manufacturing process information may be entitled to confidential treatment

BARCODE: D379979; **Reg. No. /FILE SYMBOL No.:** 87655-R; **PRODUCT:** Fomesafen Technical

Date: November 9, 2010

SUBJECT: FEE. Product Chemistry Review of Fomesafen Technical TGA/MUP

FROM: Shyam Mathur
Product Chemistry Team Leader
Technical Review Branch/RD

TO: Michael Walsh / Kathryn Montague, RM 23
Herbicide Branch / RD (7505P)

DP BARCODE: D379979
DECISION No.: 434408
Registration Number / File Symbol No.: 87655-R
PRODUCT NAME: Fomesafen Technical
PCC: 123802
REGISTRANT: Orion Fomes, LLC
USE: Herbicide
FOOD USE: Yes ☒ No ☐
MRID Numbers: 481094-01 through 481094-03

Shyam Mathur
11/16/10
[Signature]
11/16/2010

INTRODUCTION:

The registrant has submitted an application for the registration of the new manufacturing use product Fomesafen Technical is a TGA/MUP. The fomesafen will be used to formulate end use products herbicides to be used soybean. Group A and Group B data were submitted for the product with MRID Nos. 481094-01 through 481094-03. The registrant has submitted a CSF for basic formulation (dated 05-25-10) and the product label. The registrant on November 10, 2010, submitted a revised and corrected basic CSF (dated 11-10-10). The registrant has claimed that the proposed product is substantially similar to the Sharda Fomesafen Technical Herbicide (Reg. No. 82633-5). The ORNL, TN conducted the primary review on the proposed product. TRB has been asked to determine the acceptability of the product chemistry data submitted to support the revised basic CSF and determine its similarity to the registered product.

SUMMARY OF FINDINGS:

1. The registrant has submitted a revised basic formulation CSF (dated 11-10-10) for fomesafen TGA/MUP. The average purity of the active ingredient in TGA/MUP is 99.49%, as determined by the five batch analysis. However, the registrant has proposed 98.0% as the nominal concentration and the product label claim. The registrant has provided explanation for the proposed nominal concentration (see e-mail letter dated 11-10-10). The proposed certified limits for the AI and the impurities are based on the experimental data obtained from the analytical profile of five batches of fomesafen technical. The product chemistry data submitted corresponding to guideline reference 830.1550 (product identity & composition) and 830.1750 (certified limits) satisfy the data requirements of 40CFR§158.320 and 158.350 respectively [MRID No. 481094-02].
2. The registrant has submitted the specifications for all the starting materials used in the production of fomesafen technical at [REDACTED]. The product chemistry data submitted corresponding to guideline reference 830.1600 (description of material used to produce the product) satisfy the data requirements of 40CFR§ 158.325 [MRID No. 481094-02].

Manufacturing process information may be entitled to confidential treatment

BARCODE: D379979; Reg. No. /FILE SYMBOL No.: 87655-R; PRODUCT: Fomesafen Technical

3. The product chemistry data submitted corresponding to guideline reference 830.1620 (description of production process) satisfy the data requirements for 40CFR§158.330. The manufacturing process for fomesafen tgai / mup consists of three principal steps via batch process. The applicant has provided the details of the chemical process with reaction conditions, equipment used, working up procedures, and quality assurance steps [MRID No. 481094-02].

4. The product chemistry data submitted corresponding to guideline reference 830.1670 (discussion on the formation of impurities) satisfy the data requirements for 40CFR§158.340. During the production of fomesafen tgai/mup, the registrant discussed the formation of [REDACTED] impurities present at the concentration of > 0.1% including moisture. No other impurities were reported during the 5 batch analysis. The registrant has stated that there is no possibility of the formation of impurities of toxicological concern as there are no preexisting conditions or starting materials present in the production process which are required for their formation [MRID No. 481094-02].

5. The data submitted corresponding the guideline reference 830.1700 (preliminary analysis) satisfy the data requirements of 40CFR§158.345. The study was conducted under GLP requirements in compliance with 40CFR§160 and OECD requirements. The analysis study was performed by Life Scientific Ltd., Blackrock, County, Dublin, Ireland. Five representative batches of the fomesafen tgai/mup were analyzed for percent active ingredient and the impurities. The active ingredient and the organic impurities were identified and quantified by using HPLC-UV (290 nm) with external standard quantification method. The analytical methods were validated for accuracy, linearity, and precision [MRID Nos. 481094-01].

6. The data submitted corresponding the guideline reference 830.1800 (enforcement analytical method) satisfy the data requirements of 40CFR§158.355. The purity of the AI in the TGAi was determined by HPLC-UV by external standard method. The analytical method utilized a Spherisorb ODS (2) column (250 x 4.6 mm, 5 µm particle size). The UV detector was operating at 290 nm. The method was validated for precision, accuracy and linearity [MRID No. 481094-03].

7. The data cited corresponding to 830 series group B (physical-chemical properties) will be revaluated after the decision is made on the similarity issue. According to the Data Matrix, the registrant has conducted the accelerated storage stability (14 days at 54°C) which demonstrated that fomesafen is stable under these conditions no degradation was observed. The registrant must conduct one year studies corresponding to guidelines storage stability (830.6317) and corrosion characteristics (830.6320) [cited MRID No. 474091-05 & 474091-06].

Note to PM: There is confusion regarding the name of the active ingredient Fomesafen and Fomesafen Sodium and the corresponding PC Codes. These are two different chemicals and should have different PC Code numbers. Same PC Codes have been assigned for these two active ingredients in OPPIN. This problem should be resolved & new PC Code number for fomesafen must be assigned by ITRMD in OPPIN.

BARCODE: D379979; **Reg. No. /FILE SYMBOL No.:** 87655-R; **PRODUCT:** Fomesafen Technical

CONCLUSIONS:

The TRB has reviewed the product chemistry data submitted for Fomesafen TGA/MUP (produced by [REDACTED]) and has concluded that:

1. All the product chemistry data submitted corresponding to the guidelines 830 Series group A are acceptable.
2. The data cited corresponding to 830 series group B (physical-chemical properties) will be revaluated after the decision is made on the similarity issue. According to the Data Matrix, the registrant has conducted the accelerated storage stability (14 days at 54°C) which demonstrated that fomesafen is stable under these conditions no degradation was observed. The registrant must conduct one year studies corresponding to guidelines storage stability (830.6317) and corrosion characteristics (830.6320). It is recommended that the observations should be made at the intervals of 0 (initial), 3 month, 6 month, 9 month, and 12 month (final). The results must be submitted to the Agency on completion.
3. The proposed revised CSF for basic formulation (dated 11-10-10) is acceptable.
4. The substantial similarity determination of the proposed product (File symbol No. 87655-R) with the registered product with Reg. No. 82633-5 is subject to the toxic characteristics assessment by HED of the one new impurity (see Page # 17 for the name) present in the proposed fomesafen tga/mup. This one impurity is not present in the cited fomesafen product. For the structures of these impurities, please see Page # 26. There is significant difference in density values of the two products (1.28 g/cc in proposed vs 0.6766 g/ml in the cited product).

Note 1 PM: It is recommended that the HED should determine the toxic characteristics of the above mentioned impurity.

Note 2 to PM: There is confusion regarding the name of the active ingredient Fomesafen and Fomesafen Sodium and the corresponding PC Codes. These are two different chemicals and should have different PC Code numbers. Same PC Codes have been assigned for these two active ingredients in OPPIN. This problem should be resolved & new PC Code number for fomesafen must be assigned by ITRMD in OPPIN.

BARCODE: D379979; **Reg. No. /FILE SYMBOL No.:** 87655-R; **PRODUCT:** Fomesafen Technical

830.1550. Product identity & composition: (MRID No. 481094-01)

Common Name: Fomesafen

Chemical name (CAS): 5-(2-chloro-4-trifluoromethyl)phenoxy]-N-(methylsulfonyl)-2-nitrobenzamide

(IUPAC): 5-[2-chloro- α,α,α -trifluoro-p-tolyloxy)-N-methylsulfonyl-2-nitrobenzamide

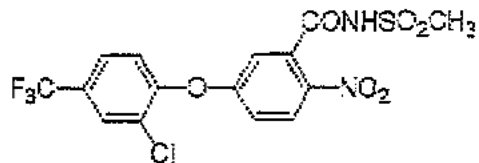
CAS No.: 72178-02-0 [given incorrectly as 108731-70-0 on the CSF and in MRID 481094-01. 108731-70-0 is the CAS No. for Fomesafen-sodium]

PC Code No.: 123802

Empirical formula: $C_{15}H_{10}ClF_3N_2O_6S$

Molecular Weight: 438.8

Structural formula:



Manufacturing process information may be entitled to confidential treatment

BARCODE: D379979; Reg. No. /FILE SYMBOL No.: 87655-R; PRODUCT: Fomesafen Technical

Table 1. Manufacturing and Impurity Data for Fomesafen Technical TGA/MUP				
GLN	Requirement	MRID	Status	Details and /or Deficiency
830.1550	Product identity and composition	481094-01	A	The NC of AI (98.0%) is supported by a 5 batch analysis and agrees with the label claim. The impurities in the product are identified. The CAS No. for the AI is incorrect on the CSF. The revised CSF has been submitted with corrected CAS No. Although CAS Nos. are not required for impurities that are not of toxicological significance, the CAS No. given for one of the impurities on the CSF is incorrect.
830.1600	Description of materials used to produce the product	481094-02	A	The description and composition for all starting materials was provided.
830.1620	Description of production process	481094-02	A	The product is produced by an integrated batch process, and full details were provided.
830.1670	Discussion of formation of impurities	481094-02	A	A complete discussion of the origin and mechanisms of formation of [REDACTED] of the impurities was provided. The origin and mechanism of formation for the remaining impurity was not provided.
830.1700	Preliminary analysis	481094-01	A	Five batches of product were analyzed for the a.i. and [REDACTED] impurities and the results support the proposed CSF. Results for the [REDACTED] impurity were not provided.
830.1750	Certified limits	481094-02	A	Certified limits for the AI, and upper certified limits for the impurities, are within the 830.1750-specified ranges. An explanation for how the upper certified limit was determined was not provided for one of the impurities.
830.1800	Enforcement analytical method	481094-03	A	HPLC-UV was used to determine the content of AI and [REDACTED] of the impurities. The method was validated for precision, linearity, and accuracy. A method to determine the [REDACTED] impurity was not provided.
A = Acceptable; N = unacceptable (see Deficiency); N/A = Not Applicable; G = Data gap; I = In progress or need upgrade; U = Up-grade (additional information required)				

BARCODE: D379979; Reg. No. /FILE SYMBOL No.: 87655-R; PRODUCT: Fomesafen Technical

830 Series Subgroup B (Physical-Chemical Properties) Table 2: Physical and Chemical Properties of : Fomesafen Technical TGA/MUP (cited)														
GLN	Requirement	MRID	Status	Result or Deficiency										
830.6302	Color	474091-05 ^a	A	White										
830.6303	Physical state	474091-05 ^a	A	Crystalline solid										
830.6304	Odor	474091-05 ^a	A	Odorless										
830.6313	Stability to normal and elevated temperatures, metals, and metal ions	474091-06	W	Accepted. TGA/MUP will not be packaged in metal containers but only in HDPE containers.										
830.6314	Oxidation/reduction: chemical incompatibility	474091-05 ^a	A	Avoid exposure to oxidizing agents										
830.6315	Flammability		N/A	Not a combustible liquid										
830.6316	Explosibility		N/A	Not subject to thermal or impact explosibility										
830.6317	Storage stability	474091-05 ^a	U	1 year study required at room temperature										
830.6319	Miscibility		N/A	Not intended for dilution in organic solvents										
830.6320	Corrosion characteristics	474091-05 ^a	U	1 year study required at room temperature										
830.7000	pH	474091-05 ^a	A	4-5 (1% in water)										
830.7050	UV/Visible absorption	474091-05	A	<u>HPLC Spectra</u> The Fomesafen reference standard gave a peak at 11.959 minutes and produced a spectral pattern with a maxima at 210nm and a small secondary maxima at 295nm which reduced to an extinction past 400nm. Sample DNA0382/1 gave a peak at 11.910 minutes. The sample produced a spectral pattern with a maxima at 210nm and a smaller secondary maxima at 295nm which reduced to an extinction at 400nm in a similar ratio to that of the reference standard.										
830.7100	Viscosity		N/A	Product is not a liquid										
830.7200	Melting point	481094-01	A	219°C (PAI)										
830.7220	Boiling point		N/A	Product is a solid										
830.7300	Density	474091-05 ^a	A	Bulk density = 1.28 g/cm ³										
830.7370	Dissociation constants in water (DC)	474091-05	A	Using the Yesuda Shedlovsky titrimetric method and 0.1g, 0.2g and 0.05g in 200ml of 50:50 Methanol/Water <table><tr><td>Sample</td><td>Dissociation Constant</td></tr><tr><td>DNA0382/1A using 0.1000g</td><td>3.375 pKa</td></tr><tr><td>DNA 0382/1B using 0.2000g</td><td>3.313 pKa</td></tr><tr><td>DNA0382/1C using 0.0500g</td><td>3.313 pKa</td></tr><tr><td>Mean:</td><td>3.334 pKa</td></tr></table>	Sample	Dissociation Constant	DNA0382/1A using 0.1000g	3.375 pKa	DNA 0382/1B using 0.2000g	3.313 pKa	DNA0382/1C using 0.0500g	3.313 pKa	Mean:	3.334 pKa
Sample	Dissociation Constant													
DNA0382/1A using 0.1000g	3.375 pKa													
DNA 0382/1B using 0.2000g	3.313 pKa													
DNA0382/1C using 0.0500g	3.313 pKa													
Mean:	3.334 pKa													
830.7550	Partition coefficient	481094-01	A	Log P = 2.9 (pH 1); <2.2 (pH 4-10) (PAI)										

BARCODE: D379979; Reg. No. /FILE SYMBOL No.: 87655-R; PRODUCT: Fomesafen Technical

830 Series Subgroup B (Physical-Chemical Properties) Table 2: Physical and Chemical Properties of : Fomesafen Technical TGA/MUP (cited)				
GLN	Requirement	MRID	Status	Result or Deficiency
830.7840	Water solubility	481094-01	A	<10 ppm (pH 4-2); ~10,000 ppm (pH 9) at 20°C (PAI)
830.7950	Vapor pressure	481094-01	A	<4 x 10 ⁻³ mPa at 20°C (PAI)

A = Acceptable; N = unacceptable (see Deficiency); N/A = Not Applicable; G = Data gap; I = In progress or need upgrade; U = Upgrade (additional information required); W = waivers

^aMRID No. as cited on EPA Form 8570-36

30-36 *Access to FIFRA health and safety data is restricted under FIFRA section 10(g)*

DATA EVALUATION RECORD

FOMESAFEN (Fomesafen Technical)

STUDY TYPES: Product Identity and Composition (OPPTS 830.1550)
Description of Materials Used to Produce the Product (OPPTS 830.1600)
Description of Production Process (830.1620)
Discussion of Formation of Impurities (OPPTS 830.1670)
Preliminary Analysis (OPPTS 830.1700)
Certified Limits (OPPTS 830.1750)
Enforcement Analytical Method (OPPTS 830.1800)
Physical and Chemical Characteristics (OPPTS 830.6302-830.7950)

MRIDs 481094-01 through 481094-03

Prepared for
Registration Division
Office of Pesticide Programs
U.S. Environmental Protection Agency
One Potomac Yard
2777 South Crystal Drive
Arlington, VA 22202

Prepared by
Toxicology and Hazard Assessment Group
Environmental Sciences Division
Oak Ridge National Laboratory
Oak Ridge, TN 37831
Task Order No. 1-8

Primary Reviewer:
Eric B. Lewis, M.S.

Signature: Eric B. Lewis
Date: NOV 03 2010

Secondary Reviewers:
Sylvia Milanez, Ph.D., D.A.B.T.

Signature: Sylvia Milanez
Date: NOV 03 2010

Robert H. Ross, M.S., Group Leader

Signature: Robert H. Ross
Date: NOV 03 2010

Quality Assurance:
Lee Ann Wilson, M.A.

Signature: L.A. Wilson
Date: NOV 03 2010

Disclaimer

This review may have been altered subsequent to the contractor's signatures above.

Oak Ridge National Laboratory managed and operated by UT-Battelle, LLC, for the U.S. Department of Energy under Contract No. DE-AC05-00OR22725.

BARCODE: D379979; **Reg. No. /FILE SYMBOL No.:** 87655-R; **PRODUCT:** Fomesafen Technical
Oak Ridge National Laboratory managed and operated by UT-Battelle, LLC., for the U.S. Department of Energy
under Contract No. DE-AC05-00OR22725.

Fomesafen Technical: 87655-R
Robert Hawk
to:
Shyam Mathur
11/10/2010 01:19 PM
Show Details

Dear Dr. Mathur,

Thank you very much for your telephone call. A corrected Confidential Statement of Formula is attached.

As we discussed, the 5-batch analysis would allow a claim of greater than 98.0% purity. However, Orion Fomes, LLC has deliberately chosen a somewhat lower number due to a consideration of enforcement analysis. Every enforcement analysis has some degree of error associated with it. If the label claim exactly matched the 5-batch analysis and if an enforcement analysis were erroneously low, this could result in unnecessary regulatory difficulties. However, the probability of such a problem occurring is lower if the label claim is slightly lower than what the 5-batch analysis would allow.

Regards.

Robert Hawk
Agent, Orion Fomes, LLC

Fomesafen Technical: 87655-R
Robert Hawk
to:
Shyam Mathur
11/10/2010 01:19 PM
[Show Details](#)

Dear Dr. Mathur,

Thank you very much for your telephone call. A corrected Confidential Statement of Formula is attached.

As we discussed, the 5-batch analysis would allow a claim of greater than 98.0% purity. However, Orion Fomes, LLC has deliberately chosen a somewhat lower number due to a consideration of enforcement analysis. Every enforcement analysis has some degree of error associated with it. If the label claim exactly matched the 5-batch analysis and if an enforcement analysis were erroneously low, this could result in unnecessary regulatory difficulties. However, the probability of such a problem occurring is lower if the label claim is slightly lower than what the 5-batch analysis would allow.

Regards.

Robert Hawk
Agent, Orion Fomes, LLC



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

November 16, 2010

MEMORANDUM

Subject: Name of Pesticide Product: FOMESAFEN TECHNICAL
EPA Reg. No. /File Symbol: 87655-R
DP Barcode: DP 379980
Decision No.: 434408
Action Code: R310
PC Code: xxxxxx¹ (Fomesafen: 98%)

¹No PC number found for Fomesafen; 123802 is for the sodium salt

From: Byron T. Backus, Ph.D., Toxicologist
Technical Review Branch
Registration Division (7505P)

Byron T. Backus
NOV-16-2010
B. Hansen

To: Michael Walsh/Kathryn Montague RM 23
Herbicide Branch
Registration Division (7505P)

Registrant: ORION FOMES, LLC

FORMULATION FROM LABEL:

<u>Active Ingredient(s):</u>	<u>% by wt.</u>
Fomesafen	98.0
<u>Other Ingredient(s):</u>	<u>2.0</u>
TOTAL	100.0

ACTION REQUESTED: The Risk Manager requests:

"TRB Toxicology: Please review the attached materials for registration of new product 87655-R. Please note the registrant is claiming similarity to 82633-5. Please determine if this new product is substantially similar to the cited product..."

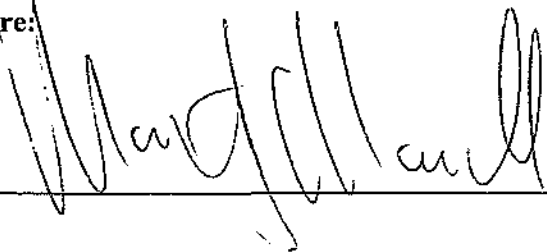
BACKGROUND:

The material received for review includes a data matrix, which indicates the registrant is citing MRIDs 46988901 through 46988906 to satisfy the 6 acute toxicity study data requirements, a proposed label (with the signal word DANGER), an application for registration (which states that this proposed product is similar or identical in composition and labelling to EPA Reg. No. 82633-5, Sharda Fomesafen Technical Herbicide), an updated CSF (dated Nov. 10, 2010) for 87655-R, and a CSF for the cited product (82633-5).

COMMENTS AND RECOMMENDATIONS:

1. After comparing the updated CSF for 87655-R and the CSF (dated April 21, 2008) for 82633-5 the Tox Team of TRB concludes that the two formulations are similar. This similarity extends to the impurities that are present.
2. Our records indicate that 82633-L (now 82633-5) was the subject of a TRB review dated January 8, 2009. In that review it was stated that: "Based on the HED analysis of the impurity profiles of the proposed and cited products, TRB has determined that the proposed product, 82633-L, and the cited product, 100-1017, are substantially similar. TRB recommends that the proposed product use the same precautionary labeling as the cited product."
3. The Toxicology Team of TRB has no objection to the registration of 87655-R as long as its label has the same precautionary and first aid statements as that of 82633-5. A comparison of the two labels indicates that they are in fact adequately similar in this respect.
4. This memorandum pertains only to the decision concerning whether the subject product is similar to the cited product from an acute toxicological view point. For the purposes of this action, TRB has made no further determination of the adequacy of the toxicological data base or the precautionary label of the cited product.
5. The CSF (dated Nov. 10, 2010) for 87655-R should also be reviewed and accepted by the TRB Chemistry Team.

Recommendation of Division Director Negotiated Due Dates		
Decision #: 434408	Registration #: 87655-R	Petition #:
Fee Category: R310	PRIA Decision Time Frame:	
Submitted by: Kathryn V. Montague, PM23	Branch: Herbicide	Today's Date: 12/28/10
Company: Orion Fomes, LLC		
Original Due Date: 1/3/10	Proposed New Due Date: 4/3/10	
Previous Negotiated Due Dates: None.		
Is the "Fix" in-house? Yes.	If not, date "Fix" expected by:	
Issue (describe in detail): Product Name: Fomesafen Technical Active Ingredient: Fomesafen <ul style="list-style-type: none"> RD's Technical Review Branch (TRB Chemistry) cited an impurity in this product's formula, which was not present in the cited product. TRB Chemistry has recommended that the Confidential Statements of Formula for this product be reviewed by the Health Effects Division to determine the toxicity characteristics of the impurity. 		
Summary of Deficiency Type(s): _____ Not Submitted (N) Deficiencies (D) Product Chemistry: _____ Acute Tox: _____ Efficacy: _____ Labeling: _____ Other (describe): <u>Additional HED Review Required</u>		
Describe Interactions with Company (describe when contacted and company's response including response to previous negotiated due dates): 12/20/10 - RD/HB signed and emailed a letter informing the registrant that their formula would require additional HED review. The registrant responded. 12/21/10 - Registrant was asked to respond to new proposed PRIA date of April 3, 2010. Registrant agrees to 60 day due date extension. 12/22/10 - Registrant informed the review cycle is 90 days and asked to cite any previous Agency decisions relating to new impurity. 12/23/10 - Registrant informs reviewer that they are seeking additional information from the producer, and believe the impurity/impurities are expected. 12/28/10 - Registrant agrees to 90 day PRIA renegotiation and asked provide whatever additional information they have to demonstrate the impurity has already been reviewed by the Agency. 12/28/10 - RD/HB provided a CBI-appropriate copy of the TRB Chemistry Review which did not include any information related to the cited product.		
Letter sent on 12/20/10 <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No and reason for none?		
Rationale for Proposed Due Date: 90 days after original PRIA due date.		
Registrant notified that this is the last negotiation? Yes <input type="checkbox"/> <input checked="" type="checkbox"/> Not Applicable		
Approve: <input checked="" type="checkbox"/>	Disapprove:	
If disapproved, action to be taken:		

OD or DOD Signature: 	Date: 12-29-10
---	--------------------------



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

OFFICE OF
PREVENTION, PESTICIDES AND
TOXIC SUBSTANCES

Mr. Robert Hawk
Registration Agent
Orion Fomes, LLC
P.O. Box 21720
Mesa, AZ 85277

26

Subject: New Product Registration; Additional Science Review Required
Product: Fomesafen Technical
EPA File Symbol: 87655-R
Submission Date: May 25, 2010
EPA Decision Number: 434408

Dear Mr. Hawk:

The Registration Division's Technical Review Branch has determined that the Confidential Statement of Formula (CSF) accompanying the submission for the product cited above requires additional Health Effects Division (HED) review. This additional review will take up to 90 days, and requires a renegotiation of the PRIA due date for this product.

The original PRIA due date of January 3, 2010 must be renegotiated and extended by 90 days to accommodate the HED review cycle. The proposed new PRIA due date is April 3, 2010.

HED will determine the toxic characteristics of an impurity cited in the CSF. It is important to note that if HED review determines that the impurities are of toxicological concern, additional data may be required and the PRIA due date may again need to be renegotiated.

If you have any questions regarding these comments or the PRIA due date, please feel free to contact Mike Walsh at 1-703-308-2972 or via email at "walsh.michael@epa.gov".

Sincerely,

Kathryn V. Montague
Product Manager (23)
Herbicide Branch
Registration Division (7505P)

Copy - Kathleen Umalle

Print Form

Please read instructions on reverse before completing form.

Form Approved OMB No. 2070-0060, Approval expires 2-28



United States
Environmental Protection Agency
Washington, DC 20480

☒ Registration
☐ Amendment
☐ Other

OPP Identifier Number

Application for Pesticide - Section I

1. Company/Product Number 87655-X	2. EPA Product Manager K. Montague	3. Proposed Classification <input type="checkbox"/> None <input checked="" type="checkbox"/> Restricted
4. Company/Product (Name) Fomesafen Technical	PM# 23	
5. Name and Address of Applicant (Include ZIP Code) Orion Fomes, LLC P. O. Box 21720 Mesa, AZ 85277 <input checked="" type="checkbox"/> Check if this is a new address	6. Expedited Review. In accordance with FIFRA Section 3(c)(3)(b)(i), my product is similar or identical in composition and labeling to: EPA Reg. No. 82633-5 Product Name Sharda Fomesafen Technical Herbicide	

Section - II

<input type="checkbox"/> Amendment - Explain below.	<input type="checkbox"/> Final printed labels in response to Agency letter dated _____
<input type="checkbox"/> Resubmission in response to Agency letter dated _____	<input type="checkbox"/> "Me Too" Application.
<input type="checkbox"/> Notification - Explain below.	<input checked="" type="checkbox"/> Other - Explain below.

Explanation: Use additional page(s) if necessary. (For section I and Section II.)

This is a registration application for a new manufacturing-use product that is substantially similar to other registered products.

Section - III

1. Material This Product Will Be Packaged In:				2. Type of Container	
Child-Resistant Packaging <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	Unit Packaging <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	Water Soluble Packaging <input type="checkbox"/> Yes <input checked="" type="checkbox"/> Text No		<input type="checkbox"/> Metal <input checked="" type="checkbox"/> Plastic <input type="checkbox"/> Glass <input type="checkbox"/> Paper <input type="checkbox"/> Other (Specify) _____	
* Certification must be submitted		If "Yes" Unit Packaging wgt.	No. per container	If "Yes" Package wgt	No. per container
3. Location of Net Contents Information <input type="checkbox"/> Label <input checked="" type="checkbox"/> Container		4. Size(s) Retail Container 40 kg (not retail)		5. Location of Label Directions <input type="checkbox"/> On Label <input checked="" type="checkbox"/> On Labeling accompanying product	
6. Manner in Which Label is Affixed to Product <input type="checkbox"/> Lithograph <input checked="" type="checkbox"/> Paper glued <input type="checkbox"/> Stenciled		<input type="checkbox"/> Other _____			

Section - IV

1. Contact Point (Complete items directly below for identification of individual to be contacted, if necessary, to process this application.)		
Name Robert Hawk	Title Agent	Telephone No. (Include Area Code) 928-342-3489
Certification I certify that the statements I have made on this form and all attachments thereto are true, accurate and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law.		6. Date Application Received (Stamped)
2. Signature 	3. Title Agent	
4. Typed Name Robert Hawk	5. Date May 25, 2010	

ORION FOMES, LLC

DATA TRANSMITTAL DOCUMENT

Name and Address of Submitter

Orion Fomes, LLC
P. O. Box 21720
Mesa, AZ 85277

Regulatory Action in Support of Which This Package is Submitted

Application for Pesticide Registration
Fomesafen Technical, EPA File Symbol 87655-x

Transmittal Date

May 25, 2010

List of Submitted Studies (3 Copies of Each)

T. Doyle, "Fomesafen Technical: Product Identification and Preliminary Analysis," Life Scientific Report QIN-001 (January 18, 2010), 122 pages, OPPTS 830.1550 and 830.1700

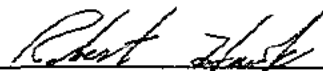
R. Hawk, "Fomesafen Technical: Product Identity, Description of Materials, Manufacturing Process, Discussion of Impurities and Certification of Limits," Report SD1004C (April 22, 2010), 124 pages, OPPTS 830.1550, 830.1600, 830.1620, 830.1670 and 830.1750

T. Doyle, "Fomesafen Technical: Enforcement Analytical Method," Life Scientific Report QIN-001NC (January 18, 2010), 19 pages, OPPTS 830.1800

Company Official:
Company Name:
Company Contact:

Robert Hawk, Agent
Orion Fomes, LLC
Robert Hawk
zaphawk@aol.com
telephone (928) 942-3489

Signature: _____



P.O. Box 21720, Mesa, Arizona 85277

OPPTS 830.218-1289

May 25, 2010

Document Processing Desk (APPL)
Office of Pesticide Programs (P7504C)
Environmental Protection Agency
Room S-4900, One Potomac Yard (South Building)
2777 S. Crystal Drive
Arlington, VA 22202

Attn: Kathryn Montague (PM 23), Registration Division

Dear Ms. Montague:

Subject: Fomesafen Technical: Registration Application

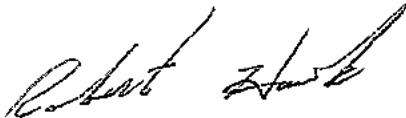
Orion Fomes, LLC wishes to apply for the registration of a new manufacturing-use product, Fomesafen Technical. In support of this application we have enclosed the following:

- Application for Pesticide Registration (8570-1)
- Confidential Statement of Formula (8570-4)
- Certification with Respect to Citation of Data (8570-34)
- Data Matrix (8570-35)
- Summary of the Physical/Chemical Properties (8570-36)
- Self-Certification Statement for the Physical/Chemical Properties (8570-37)
- Proposed label (6 copies)
- Supporting studies (3 copies, with Data Transmittal Document)

We have concluded that this regulatory action falls in PRIA II Category R310, for which a fee of \$4,360 is required. Please find proof of payment enclosed.

Please contact me if you have any questions.

Sincerely,



Robert Hawk, Agent
Orion Fomes, LLC

ORION FOMES, LLC

DATA TRANSMITTAL DOCUMENT

Name and Address of Submitter

Orion Fomes, LLC
P. O. Box 21720
Mesa, AZ 85277

Regulatory Action in Support of Which This Package is Submitted

Application for Pesticide Registration
Fomesafen Technical, EPA File Symbol 87655-x

Transmittal Date

May 25, 2010

List of Submitted Studies (3 Copies of Each)

- 48109401** T. Doyle, "Fomesafen Technical: Product Identification and Preliminary Analysis," Life Scientific Report QIN-001 (January 18, 2010), 122 pages, OPPTS 830.1550 and 830.1700
- 48109402** R. Hawk, "Fomesafen Technical: Product Identity, Description of Materials, Manufacturing Process, Discussion of Impurities and Certification of Limits," Report SD1004C (April 22, 2010), 124 pages, OPPTS 830.1550, 830.1600, 830.1620, 830.1670 and 830.1750
- 48109403** T. Doyle, "Fomesafen Technical: Enforcement Analytical Method," Life Scientific Report QIN-001NC (January 18, 2010), 19 pages, OPPTS 830.1800

Company Official:
Company Name:
Company Contact:

Robert Hawk, Agent
Orion Fomes, LLC
Robert Hawk
zaphawk@aol.com
telephone (928) 942-3489

Signature: _____



P. O. Box 21720, Mesa, Arizona 85277

tel: (480)-218-2289

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY 1200 Pennsylvania Avenue, N.W. WASHINGTON, D.C. 20460

Paperwork Reduction Act Notice: The public reporting burden for this collection of information is estimated to average 1.25 hours per response for registration and 0.25 hours per response for reregistration and special review activities, including time for reviewing the instructions and completing the necessary forms. Send comments regarding burden estimate or any other aspect of this collection of information, including suggestions for reducing the burden to: Director, Collection Strategies Division (2822T), U.S. Environmental Protection Agency, 1200 Pennsylvania Avenue, N.W., Washington, DC 20460. Do not send the completed form to this address.

Certification with Respect to Citation of Data

Applicant's/Registrant's Name, Address, and Telephone Number Orion Fomes, LLC P. O. Box 21720 Mesa, AZ 85277	EPA Registration Number/File Symbol 87655-R
Active Ingredient(s) and/or representative test compound(s) fomesafen	Date June 10, 2010
General Use Pattern(s) (list all those claimed for this product using 40 CFR Part 158) terrestrial crop use	Product Name Fomesafen Technical

NOTE: If your product is a 100% repackaging of another purchased EPA-registered product labeled for all the same uses on your label, you do not need to submit this form. You must submit the Formulator's Exemption Statement (EPA Form 8570-27).

I am responding to a Data-Call-In Notice, and have included with this form a list of companies sent offers of compensation (the Data Matrix form should be used for this purpose). ☐

SECTION I: METHOD OF DATA SUPPORT (Check one method only)

I am using the cite-all method of support, and have included with this form a list of companies sent offers of compensation (the Data Matrix form should be used for this purpose). <input type="checkbox"/>	I am using the selective method of support (or cite-all option under the selective method), and have included with this form a completed list of data requirements (the Data Matrix form must be used). <input checked="" type="checkbox"/>
--	---

SECTION II: GENERAL OFFER TO PAY

[Required if using the cite-all method or when using the cite-all option under the selective method to satisfy one or more data requirements] I hereby offer and agree to pay compensation, to other persons, with regard to the approval of this application, to the extent required by FIFRA. ☒

SECTION III: CERTIFICATION

I certify that this application for registration, this form for reregistration, or this Data-Call-In response is supported by all data submitted or cited in the application for registration, the form for reregistration, or the Data-Call-In response. In addition, if the cite-all option or cite-all option under the selective method is indicated in Section I, this application is supported by all data in the Agency's files that (f) concern the properties or effects of this product or an identical or substantially similar product, or one or more of the ingredients in this product; and (2) is a type of data that would be required to be submitted under the data requirements in effect on the date of approval of this application if the application sought the initial registration of a product of identical or similar composition and uses.

I certify that for each exclusive use study cited in support of this registration or reregistration, that I am the original data submitter or that I have obtained the written permission of the original data submitter to cite that study.

I certify that for each study cited in support of this registration or reregistration that is not an exclusive use study, either: (a) I am the original data submitter; (b) I have obtained the permission of the original data submitter to use the study in support of this application; (c) all periods of eligibility for compensation have expired for the study; (d) the study is in the public literature; or (e) I have notified in writing the company that submitted the study and have offered (i) to pay compensation to the extent required by sections 3(c)(1)(F) and/or 3(c)(2)(B) of FIFRA; and (ii) to commence negotiations to determine the amount and terms of compensation, if any, to be paid for the use of the study.

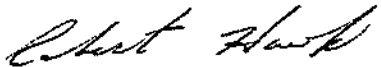
I certify that in all instances where an offer of compensation is required, copies of all offers to pay compensation and evidence of their delivery in accordance with sections 3(c)(1)(F) and/or 3(c)(2)(B) of FIFRA are available and will be submitted to the Agency upon request. Should I fail to produce such evidence to the Agency upon request, I understand that the Agency may initiate action to deny, cancel or suspend the registration of my product in conformity with FIFRA.

I certify that the statements I have made on this form and all attachments to it are true, accurate, and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law.

Signature 	Date June 10, 2010	Typed or Printed Name and Title Robert Hawk, Agent
--	-----------------------	---

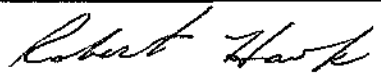
Paperwork Reduction Act Notice: The public reporting burden for this collection of information is estimated to average 0.25 hours per response for registration activities and 0.25 hours per response for reregistration and special review activities, including time for reading the instructions and completing the necessary forms. Send comments regarding the burden estimate or any other aspect of this collection of information, including suggestions for reducing the burden to: Director, OPPE Information Management Division (2 f37), U.S. Environmental Protection Agency, 401 M Street, S.W., Washington, DC 20460. Do not send the form to this address.

DATA MATRIX

Date 5/25/2010			EPA Reg. No./File Symbol 87655-x		Page 1 of 4
Applicant's/Registrant's Name & Address Orion Fomes, LLC P. O. Box 21720 Mesa, AZ 85277			Product Fomesafen Technical		
Ingredient fomesafen					
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
830.f550	product identification and disclosure of ingredients	NEW	Orion Fomes, LLC	OWN	
830.1600	description of beginning materials	NEW	Orion Fomes, LLC	OWN	
830.1620	description of manufacturing process	NEW	Orion Fomes, LLC	OWN	
830.1670	discussion of formation of impurities	NEW	Orion Fomes, LLC	OWN	
830.1700	preliminary analysis	NEW	Orion Fomes, LLC	OWN	
830.1750	certification of limits	NEW	Orion Fomes, LLC	OWN	
830.1800	enforcement analytical method	NEW	Orion Fomes, LLC	OWN	
830.6302	color	47409105	Sharda Worldwide Exports Pvt., Ltd.	PAY	
830.6303	physical state	47409105	Sharda Worldwide Exports Pvt., Ltd.	PAY	
830.6304	odor	47409105	Sharda Worldwide Exports Pvt., Ltd.	PAY	
830.6313	stability to normal and elevated temperatures	47409105 47409106	Sharda Worldwide Exports Pvt., Ltd.	PAY	
830.6314	oxidation / reduction: chemical incompatibility	47409105	Sharda Worldwide Exports Pvt., Ltd.	PAY	
830.6315	flammability		not applicable; not a combustible liquid		
Signature 			Name and Title: Robert Hawk, Agent, Orion Fomes, LLC		Date: 5/25/2010

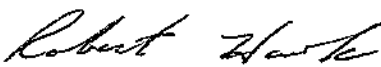
Paperwork Reduction Act Notice: The public reporting burden for this collection of information is estimated to average 0.25 hours per response for registration activities and 0.25 hours per response for reregistration and special review activities, including time for reviewing the instructions and completing the necessary forms. Send comments regarding the burden estimate or any other aspect of this collection of information, including suggestions for reducing the burden to: Director, OPPE Information Management Division (2137), U.S. Environmental Protection Agency, 401 M Street, S.W., Washington, DC 20460. Do not send the form to this address.

DATA MATRIX

Date 5/25/2010			EPA Reg. No./File Symbol 87655-x		Page 2 of 4
Applicant's/Registrant's Name & Address Orion Fomes, LLC P. O. Box 21720 Mesa, AZ 85277			Product Fomesafen Technical		
Ingredient fomesafen					
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
830.6316	explosibility		not applicable; not potentially explosive		
830.6317	storage stability	47409105 47409106	Sharda Worldwide Exports Pvt., Ltd.	PAY	
630.6319	miscibility		not applicable; not an emulsifiable liquid		
830.6320	corrosion characteristics	47409106	Sharda Worldwide Exports Pvt., Ltd.	PAY	
830.6321	dielectric breakdown voltage		not applicable; not an end-use product		
830.7000	pH	47409105	Sharda Worldwide Exports Pvt., Ltd.	PAY	
830.7050	UV / visible absorption	47409105	Sharda Worldwide Exports Pvt., Ltd.	PAY	
830.7100	viscosity		not applicable; not a liquid		
830.7200	melting point	47409105	Sharda Worldwide Exports Pvt., Ltd.	PAY	
830.7220	boiling point		not applicable; not a liquid at room temperature		
830.7300	density / relative density	47409105	Sharda Worldwide Exports Pvt., Ltd.	PAY	
830.7370	dissociation constant in water	47409105	Sharda Worldwide Exports Pvt., Ltd.	PAY	
830.7570	octanol / water partition coefficient	47409105	Sharda Worldwide Exports Pvt., Ltd.	PAY	
Signature 			Name and Title: Robert Hawk, Agent, Orion Fomes, LLC		Date: 5/25/2010

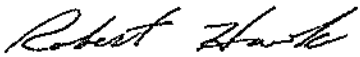
Paperwork Reduction Act Notice: The public reporting burden for this collection of information is estimated to average 0.25 hours per response for registration activities and 0.25 hours per response for reregistration and special review activities, including time for reading the instructions and completing the necessary forms. Send comments regarding the burden estimate or any other aspect of this collection of information, including suggestions for reducing the burden to: Director, OPPE Information Management Division (2137), U.S. Environmental Protection Agency, 401 M Street, S.W., Washington, DC 20460. Do not send the form to this address.

DATA MATRIX

Date 5/25/2010			EPA Reg. No./File Symbol 87655-x		Page 3 of 4
Applicant's/Registrant's Name & Address Orion Fomes, LLC P. O. Box 21720 Mesa, AZ 85277			Product Fomesafen Technical		
Ingredient fomesafen					
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
830.7840	water solubility	47409105	Sharda Worldwide Exports Pvt., Ltd.	PAY	
830.7860	water solubility	see 830.7840			
830.7950	vapor pressure	47409105	Sharda Worldwide Exports Pvt., Ltd.	PAY	
870.1100	acute oral toxicity	46988901	Syngenta Crop Protection, Inc.	PAY	
870.1200	acute dermal toxicity	46988902	Syngenta Crop Protection	PAY	
870.1300	acute inhalation toxicity	46988903	Syngenta Crop Protection	PAY	
870.2400	acute eye irritation	46988904	Syngenta Crop Protection	PAY	
870.2500	acute dermal irritation	46988905	Syngenta Crop Protection	PAY	
870.2600	skin sensitization	46988906	Syngenta Crop Protection	PAY	
Signature 			Name and Title: Robert Hawk, Agent, Orion Fomes, LLC		Date: 5/25/2010

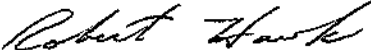
Paperwork Reduction Act Notice: The public reporting burden for this collection of information is estimated to average 0.25 hours per response for registration activities and 0.25 hours per response for reregistration and special review activities, including time for reviewing the instructions and completing the necessary forms. Send comments regarding the burden estimate or any other aspect of this collection of information, including suggestions for reducing the burden to: Director, OPPE Information Management Division (2137), U.S. Environmental Protection Agency, 401 M Street, S.W., Washington, DC 20460. Do not send the form to this address.

DATA MATRIX

Date 5/25/2010			EPA Reg. No./File Symbol 87655-x		Page 4 of 4
Applicant's/Registrant's Name & Address Orion Fomes, LLC P. O. Box 21720 Mesa, AZ 85277			Product Fomesafen Technical		
Ingredient fomesafen					
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
Series 875: cite-all Series 810: cite-all Series 835: cite-all Series 840: cite-all Series 850: cite-all Series 860: cite-all Series 875: cite-all	Toxicology: generic data Product Performance: generic data Fate, Transport and Transformation: generic data Spray Drift: generic data Ecological Effects: generic data Residue Chemistry: generic data Occupational and Residential Exposure: generic data	multiple	Syngenta Crop Protection, Inc.	PAY	
			Spray Drift Task Force	PAY	
			Chemnova, Inc.	PAY	
			Outdoor Residential Exposure Task Force	PAY	
			Agricultural Reentry Task Force	PAY	
			FIFRA Endangered Species Task Force	PAY	
			Agricultural Handlers Exposure Task Force	PAY	
			Sharda Worldwide Exports Pvt., Ltd	PAY	
			Sharda USA LLC	PAY	
Signature 			Name and Title: Robert Hawk, Agent, Orion Fomes, LLC		Date: 5/25/2010

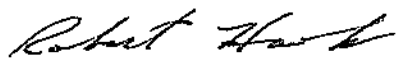
Paperwork Reduction Act Notice: The public reporting burden for this collection of information is estimated to average 0.25 hours per response for registration activities and 0.25 hours per response for reregistration and special review activities, including time for reading the instructions and completing the necessary forms. Send comments regarding the burden estimate or any other aspect of this collection of information, including suggestions for reducing the burden to: Director, OPPE Information Management Division (2137), U.S. Environmental Protection Agency, 401 M Street, S.W., Washington, DC 20460. Do not send the form to this address.

DATA MATRIX

Date 5/25/2010			EPA Reg. No./File Symbol 87655-x		Page 1 of 4
Applicant's/Registrant's Name & Address Orion Fomes, LLC P. O. Box 21720 Mesa, AZ 85277			Product Fomesafen Technical		
Ingredient fomesafen					
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
			Orion Fomes, LLC	OWN	
			Orion Fomes, LLC	OWN	
			Orion Fomes, LLC	OWN	
			Orion Fomes, LLC	OWN	
			Orion Fomes, LLC	OWN	
			Orion Fomes, LLC	OWN	
			Orion Fomes, LLC	OWN	
			Orion Fomes, LLC	OWN	
			Sharda Worldwide Exports Pvt., Ltd.	PAY	
			Sharda Worldwide Exports Pvt., Ltd.	PAY	
			Sharda Worldwide Exports Pvt., Ltd.	PAY	
			Sharda Worldwide Exports Pvt., Ltd.	PAY	
			Sharda Worldwide Exports Pvt., Ltd.	PAY	
			not applicable; not a combustible liquid		
Signature 			Name and Title: Robert Hawk, Agent, Orion Fomes, LLC		Date: 5/25/2010

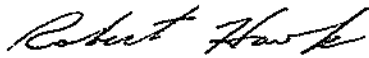
Paperwork Reduction Act Notice: The public reporting burden for this collection of information is estimated to average 0.25 hours per response for registration activities and 0.25 hours per response for reregistration and special review activities, including time for reading the instructions and completing the necessary forms. Send comments regarding the burden estimate or any other aspect of this collection of information, including suggestions for reducing the burden to: Director, OPPE Information Management Division (2137), U.S. Environmental Protection Agency, 401 M Street, S.W., Washington, DC 20460. Do not send the form to this address.

DATA MATRIX

Date 5/25/2010			EPA Reg. No./File Symbol 87655-x		Page 2 of 4
Applicant's/Registrant's Name & Address Orion Fomes, LLC P. O. Box 21720 Mesa, AZ 85277			Product Fomesafen Technical		
Ingredient fomesafen					
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
			not applicable; not potentially explosive		
			Sharda Worldwide Exports Pvt., Ltd.	PAY	
			not applicable; not an emulsifiable liquid		
			Sharda Worldwide Exports Pvt., Ltd.	PAY	
			not applicable; not an end-use product		
			Sharda Worldwide Exports Pvt., Ltd.	PAY	
			Sharda Worldwide Exports Pvt., Ltd.	PAY	
			not applicable; not a liquid		
			Sharda Worldwide Exports Pvt., Ltd.	PAY	
			not applicable; not a liquid at room temperature		
			Sharda Worldwide Exports Pvt., Ltd.	PAY	
			Sharda Worldwide Exports Pvt., Ltd.	PAY	
			Sharda Worldwide Exports Pvt., Ltd.	PAY	
Signature 			Name and Title: Robert Hawk, Agent, Orion Fomes, LLC		Date: 5/25/2010

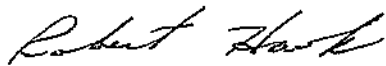
Paperwork Reduction Act Notice: The public reporting burden for this collection of information is estimated to average 0.25 hours per response for registration activities and 0.25 hours per response for reregistration and special review activities, including time for reading the instructions and completing the necessary forms. Send comments regarding the burden estimate or any other aspect of this collection of information, including suggestions for reducing the burden to: Director, OPPE Information Management Division (2137), U.S. Environmental Protection Agency, 401 M Street, S.W., Washington, DC 20460. Do not send the form to this address.

DATA MATRIX

Date 5/25/2010			EPA Reg. No./File Symbol 87655-x		Page 3 of 4
Applicant's/Registrant's Name & Address Orion Fomes, LLC P. O. Box 21720 Mesa, AZ 85277			Product Fomesafen Technical		
Ingredient fomesafen					
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
			Sharda Worldwide Exports Pvt., Ltd.	PAY	
			Sharda Worldwide Exports Pvt., Ltd.	PAY	
			Syngenta Crop Protection, Inc.	PAY	
			Syngenta Crop Protection	PAY	
			Syngenta Crop Protection	PAY	
			Syngenta Crop Protection	PAY	
			Syngenta Crop Protection	PAY	
			Syngenta Crop Protection	PAY	
Signature 			Name and Title: Robert Hawk, Agent, Orion Fomes, LLC		Date: 5/25/2010

Paperwork Reduction Act Notice: The public reporting burden for this collection of information is estimated to average 0.25 hours per response for registration activities and 0.25 hours per response for reregistration and special review activities, including time for reading the instructions and completing the necessary forms. Send comments regarding the burden estimate or any other aspect of this collection of information, including suggestions for reducing the burden to: Director, OPPE Information Management Division (2137), U.S. Environmental Protection Agency, 401 M Street, S.W., Washington, DC 20460. Do not send the form to this address.

DATA MATRIX

Date 5/25/2010			EPA Reg. No./File Symbol 87655-x		Page 4 of 4
Applicant's/Registrant's Name & Address Orion Fomes, LLC P. O. Box 21720 Mesa, AZ 85277			Product Fomesafen Technical		
Ingredient fomesafen					
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
			Syngenta Crop Protection, Inc.	PAY	
			Spray Drift Task Force	PAY	
			Chemnova, Inc.	PAY	
			Outdoor Residential Exposure Task Force	PAY	
			Agricultural Reentry Task Force	PAY	
			FIFRA Endangered Species Task Force	PAY	
			Agricultural Handlers Exposure Task Force	PAY	
			Sharda Worldwide Exports Pvt., Ltd	PAY	
			Sharda USA LLC	PAY	
Signature 			Name and Title: Robert Hawk, Agent, Orion Fomes, LLC		Date: 5/25/2010



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
401 M Street, S.W.
WASHINGTON, D.C. 20460

Paperwork Reduction Act Notice: The public reporting burden for this collection of information is estimated to average 1 hour per response for registration activities and 1 hour per response for reregistration and special review activities, including time for reading the instructions and completing the necessary forms. Send comments regarding burden estimate or any other aspect of this collection of information, including suggestions for reducing the burden to: Director, OPPE Information Management Division (2137), U.S. Environmental Protection Agency, 401 M Street, S.W., Washington, DC 20460. Do not send the completed form to this address.

SUMMARY OF THE PHYSICAL/CHEMICAL PROPERTIES (PR Notice 98-1)

1. PRODUCT NAME: Fomesafen Technical		2. Reg. No. 87655-x
3. COMPANY NAME: Orion Fomes, LLC		4. SUBMISSION DATE: May 25, 2010
5. FIRST SUBMISSION <input checked="" type="checkbox"/>	7. PESTICIDE TYPE: herbicide	10. REGISTRATION <input checked="" type="checkbox"/>
6. RESUBMISSION <input type="checkbox"/>		
8. FORMULATED MANUFACTURING-USE PRODUCT <input checked="" type="checkbox"/> or 9. END-USE PRODUCT <input type="checkbox"/>		11. REREGISTRATION <input type="checkbox"/>
13. PRODUCT MANAGER OR CHEMICAL REVIEW MANAGER #/NAME (IF KNOWN): K. Montague (23)		12. REREG CASE #
14. GUIDELINE REFERENCE NO. (GRN)/TITLE	15. VALUE or QUALITATIVE DESCRIPTION/METHOD(s) USED WHERE APPLICABLE AND REFERENCES	16. MRID or REPORT NO.
Group B, Series 830-Physical and Chemical Properties (40 CFR 158.190)		
-6302 Color	white (visual)	47409105
-6303 Physical State	solid (crystalline) (visual)	47409105
-6304 Odor	odorless (sensory)	47409105
-6314 Oxidation/Reduction: Chemical Incompatibility	avoid exposure to oxidizing agents	47409105
-6315 Flammability/Flame Extension	not applicable; not a combustible liquid	
-6316 Explodability	not applicable; not subject to thermal or impact explodability	
-6317 Storage Stability	stable >1 year at 25 degrees C (by chemical analysis)	47409105
-6319 Miscibility	not applicable; not intended for dilution in organic solvents	
-6320 Corrosion Characteristics	not corrosive to its packaging in 1 year (visual and gravimetric)	47409105
-6321 Dielectric Breakdown Voltage	not applicable; not intended for household use	
-7000 pH	4 - 5 (1% in water) (pH probe)	47409105
-7100 Viscosity	not applicable; not a liquid	
-7300 Density/Relative Density/Bulk Density	bulk density 1.28 g/cm ³ (gravimetric)	47409105



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
1200 Pennsylvania Avenue, N.W.
WASHINGTON, D.C. 20460

Paperwork Reduction Act Notice: The public reporting burden for this collection of information is estimated to average 0.25 hours per response for registration activities and 0.25 hours per response for reregistration and special review activities, including time for reading the instructions and completing the necessary forms. Send comments regarding the burden estimate or any other aspect of this collection of information, including suggestions for reducing the burden to: Director, Collection Strategies Division (2822T), U.S. Environmental Protection Agency, 1200 Pennsylvania Avenue, N.W., Washington, DC 20460. Do not send the form to this address.

**SELF-CERTIFICATION STATEMENT FOR THE
 PHYSICAL/CHEMICAL PROPERTIES (PR NOTICE 98-1)**

Product Name: **Fomesafen Technical**

Reg. No./File Symbol No.
 (if known) or Company No. **87655-x**

SELF-CERTIFICATION STATEMENT:

I certify that the reported information on the "Summary Form" represents a true and accurate record of the test results of studies generated or owned by (Company Name): Sharda Worldwide Exports Pvt., Ltd. and that the values of the properties reported are reliable.

I further certify that such data were generated in substantial conformity with OPPTS Test Guideline Series 830 Product Properties, applicable to my product, and in effect at the time of submission.

As a condition of registration, EPA may, by order, (1) withdraw a pending registration, (2) suspend the registration of this product without opportunity for hearing, or (3) assess civil penalties provided for in section 14 of FIFRA for violations of section 12(a)(2)(N) of FIFRA without opportunity for hearing, if I have not submitted to EPA within thirty (30) days of receipt of a request by the Agency, or within a specified time agreed to by the Agency, test results of studies summarized in the "Summary Form."

As a condition of registration, EPA may, by order, (1) withdraw a pending registration, (2) suspend the registration of this product without opportunity for hearing, or (3) assess civil penalties provided for in section 14 of FIFRA for violations of sections 12(a)(2)(N), 12(a)(2)(Q), or 12(a)(2)(R) of FIFRA without opportunity for hearing, if I fail to provide to EPA within thirty (30) days of receipt of a notification of error, or within a specified time agreed to by the Agency, information that EPA determines is required to correct the error.

Type Applicant's Name: **Robert Hawk**

Title: **Agent**

Telephone No. **928-342-3489**

Applicant's Signature:

Robert Hawk

Date: **May 25, 2010**

draft Orion Fomes Fomesafen label May 25, 2010

FOMESAFEN TECHNICAL

FOR FORMULATING USE ONLY

ACTIVE INGREDIENT

Fomesafen [5-[2-chloro-4-trifluoromethyl)phenoxy]-N-(methylsulfonyl)-2-nitrobenzamide].....98.0%

OTHER INGREDIENTS:.....2.0%**TOTAL**..... 100.0%

KEEP OUT OF REACH OF CHILDREN

DANGER/PELOGRO

Si usted no entiende la etiqueta, busque a alguien para que se la explique a usted en detalle.

(If you do not understand the label, find someone to explain it to you in detail.)

See Additional Precautionary Statements and Directions for Use on label.

FIRST AID

IF IN EYES	<ul style="list-style-type: none"> • Hold eye open and rinse slowly and gently with water for 15-20 minutes. • Remove contact lenses, if present, after the first 5 minutes, then continue rinsing eye. • Call a poison control center or doctor for treatment advice.
IF SWALLOWED	<ul style="list-style-type: none"> • Call a poison control center or doctor immediately for treatment advice. • Have person sip a glass of water if able to swallow. • Do not induce vomiting unless told to do so by a poison control center or doctor. • Do not give anything by mouth to an unconscious person.
IF ON SKIN OR CLOTHING	<ul style="list-style-type: none"> • Take off contaminated clothing. • Rinse skin immediately with plenty of water for 15-20 minutes. • Call a poison control center or doctor for treatment advice.
IF INHALED	<ul style="list-style-type: none"> • Move person to fresh air. • If person is not breathing, call 911 or an ambulance, then give artificial respiration, preferably by mouth-to-mouth if possible. • Call a poison control center or doctor for further treatment advice.

For **MEDICAL** Emergencies 24 Hours a Day Call a Poison Control Center at 1-800-222-1222.
 For **CHEMICAL** Emergency Assistance (Spill, Fire or Accident) Call ChemTrec at 1-800-424-9300
 Have the product container or label with you when calling a Poison Control Center or doctor or going for treatment.

NOTE TO PHYSICIAN

Probable mucosal damage may contraindicate the use of gastric lavage.

Orion Fomes, LLC
P.O. Box 21720
Mesa, AZ 85277

EPA Reg. No. 87655-x
EPA Est. No. xxxxxxxx
Net Contents: 30 kg

Tel. 480-218-4289

PRECAUTIONARY STATEMENTS

HAZARDS TO HUMANS AND DOMESTIC ANIMALS

CORROSIVE. CAUSES IRREVERSIBLE EYE DAMAGE. DUE TO CORROSIVE NATURE, MAY BE HARMFUL OR FATAL IF SWALLOWED. HARMFUL IF INHALED OR ABSORBED THROUGH SKIN. Do not get in eyes, on skin or on clothing. Avoid breathing vapor.

PERSONAL PROTECTIVE EQUIPMENT (PPE)

Manufacturers and other handlers must wear:

- Coveralls
- Waterproof gloves
- Shoes plus socks
- Protective eyewear

Discard clothing and other absorbent materials that have been heavily contaminated with this technical material. Do not reuse them.

USER SAFETY RECOMMENDATIONS

Users should:

- Wash thoroughly with soap and water after handling and before eating, drinking, chewing gum, using tobacco or using the toilet.
- Remove clothing immediately if pesticide gets inside. Then wash thoroughly and put on clean clothing.
- Remove PPE immediately after handling this product. Wash the outside of gloves before removing. As soon as possible, wash thoroughly and change into clean clothing.

ENVIRONMENTAL HAZARDS

Do not discharge effluent containing this product into lakes, streams, ponds, estuaries, oceans or other waters unless in accordance with the requirements of a National Pollutant Discharge Elimination System (NPDES) permit and the permitting authority has been notified in writing prior to discharge. Do not discharge effluent containing this product to sewer systems without previously notifying the local sewage treatment plant authority. For guidance contact your State Water Board or Regional Office of the EPA.

DIRECTIONS FOR USE

It is a violation of federal law to use this product in a manner inconsistent with its labeling.

Formulators using this product are responsible for obtaining EPA registration for their formulated products.

Fomesafen Technical is intended solely for the formulation into herbicide products intended for the following uses:

Terrestrial Food Use: Soybeans

Uses for which the USEPA has accepted the required data and/or citations of data that the formulator has submitted in support of registration, and uses for experimental purposes that are in compliance with USEPA requirements.

STORAGE AND DISPOSAL

Do not contaminate water, food, or feed by storage, disposal, or cleaning of equipment.

PESTICIDE STORAGE: Store above 32°F in original container only. Keep container closed when not in use. Do not store near food or feed. In case of spill on floor or paved surfaces, sweep up and remove to chemical waste area.

PESTICIDE DISPOSAL: Pesticide wastes are acutely toxic. Improper disposal of excess pesticide, spray mixture, or rinsate is a violation of Federal law. If these wastes cannot be disposed of by use according to label instructions, contact your State Pesticide or Environmental Control Agency or the Hazardous Waste representative at the nearest EPA Regional Office for guidance.

CONTAINER DISPOSAL: Nonrefillable container. Do not reuse empty container.

Triple rinse as follows: Empty the remaining contents into application equipment or a mix tank. Fill the container ¼ full with water. Replace and tighten closures. Tip container on its side and roll it back and forth, ensuring at least one complete revolution, for 30 seconds. Stand the container on its end and tip it back and forth several times. Empty the rinsate into the application equipment or a mix tank to store rinsate for later use or disposal. Drain for 10 seconds after the flow begins to drip. Repeat this procedure two more times.

Pressure rinse as follows: Empty the remaining contents into application or a mix tank. Hold container upside down over mix tank or collect rinsate for later use or disposal. Insert pressure rinsing nozzle in the side of the container and rinse at about 40 PSI for at least 30 seconds. Drain for 10 seconds after the flow begins to drip.

DISCLAIMER OF WARRANTIES: TO THE EXTENT CONSISTENT WITH APPLICABLE LAW, ORION FOMES LLC MAKES NO OTHER WARRANTIES, EXPRESS OR IMPLIED, OF MERCHANTABILITY OR OF FITNESS FOR A PARTICULAR PURPOSE OR OTHERWISE, THAT EXTEND BEYOND THE STATEMENTS MADE ON THIS LABEL. No agent of Orion Fomes LLC is authorized to make any warranties beyond those contained herein or to modify the warranties contained herein.

TO THE EXTENT CONSISTENT WITH APPLICABLE LAW, ORION FOMES LLC DISCLAIMS ANY LIABILITY WHATSOEVER FOR SPECIAL, INCIDENTAL OR CONSEQUENTIAL DAMAGES RESULTING FROM THE USE OR HANDLING OF THIS PRODUCT.

LIMITATIONS OF LIABILITY: TO THE EXTENT CONSISTENT WITH APPLICABLE LAW, THE EXCLUSIVE REMEDY OF THE USER OR BUYER FOR ANY AND ALL LOSSES, INJURIES OR DAMAGES RESULTING FROM THE USE OR HANDLING OF THIS PRODUCT, WHETHER IN CONTRACT, WARRANTY, TORT, NEGLIGENCE, STRICT LIABILITY OR OTHERWISE, SHALL NOT EXCEED THE PURCHASE PRICE PAID, OR AT ORION FOMES LLC'S ELECTION, THE REPLACEMENT OF PRODUCT.



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

June 2, 2010

OFFICE OF
PREVENTION, PESTICIDES AND
TOXIC SUBSTANCES

PLEASE RETURN A COPY OF THIS LETTER WITH PAYMENT
Or Pay On-Line at www.Pay.Gov (See Below for Details)

OPP Decision Number: D-434408
EPA File Symbol or Registration Number: 87655-R
Product Name: FOMESAFEN TECHNICAL
EPA Receipt Date: 28-May-2010
EPA Company Number: 87655
Company Name: ORION FOMES, LLC

VASO STOJIC
ORION FOMES, LLC
PO Box 21720
MESA, AZ 85277-

SUBJECT: Receipt of Registration Application Subject to Registration Service Fee

Dear Registrant:

The Office of Pesticide Programs has received your application for registration. If you submitted data with this application, the results of the PRN-86-5 screen will be communicated separately. During the administrative screen, the Office of Pesticide Programs has determined that this Action is subject to a Pesticide Registration Service Fee as defined in the Pesticide Registration Improvement Act.

The Action has been identified as Action Code: R310

NEW PRODUCT;NON-FAST TRACK (INCLUDES REVIEWS OF PRODUCT
CHEMISTRY;ACUTE TOXICITY;PUBLIC HEALTH PEST EFFICACY);

Please remit payment in the amount of: \$218 (\$4,578 fee minus \$4,360 previously paid) to:

By USPS:
USEPA Washington Finance Center
Pesticide Registration Service Fee
PO Box 979074
St. Louis, MO 63197-9000

By Courier:
U.S. Bank
Government Lockbox 979074
1005 Convention Plaza
SL-MO-C2-GL
St. Louis, MO 63197
Telephone: (412) 236-2294

All payments must be in United States currency by check, bank draft, or money order drawn to the order of the Environmental Protection Agency. To ensure proper credit, please write the OPP DECISION NUMBER on your check, and enclose a copy of this letter with your payment.

Effective November 1, 2006, fees may be paid on-line via credit card or electronic fund transfer. To submit a payment on-line, visit www.pay.gov. From the pay.gov home page, select "search by form name." From the next page, select "P," then click on "Pesticide Registration Improvement Act. Fee Payment" and complete the form, making certain to use the decision number and registration number on the invoice you receive from the Pesticide Program in the space provided.

You may be eligible for a partial waiver of the registration service fee if, for example, you qualify as a small business or are applying for a minor use, or if your application is solely associated with an IR-4 tolerance petition. Please be advised that if you intend to request a waiver, you must do so in writing within 15 days of receipt of this invoice instead of remitting the amount indicated above. OPP will not consider waiver requests after the registration service fee has been paid. Information regarding eligibility and how to request and document a fee waiver is available on the OPP Fee for Service web site at www.epa.gov/pesticides/fees.

Please send Registration Service Fee Waiver requests to:

By USPS:
Document Processing Desk (WAIVER)
Office of Pesticide Programs (7504C)
U.S. Environmental Protection Agency
1200 Pennsylvania Ave NW
Washington, DC 20460

By Courier:
Document Processing Desk (WAIVER)
Office of Pesticide Programs (7504C)
U.S. Environmental Protection Agency
Room S4900 Potomac Yard 1
2777 S. Crystal Dr.
Arlington, VA 22202

A PRIA decision time review period will not start until a fee waiver is granted and/or the Agency receives certification that the outstanding fee has been paid. If the Agency does not receive certification of payment for this action or a fee waiver request within the next 30 days, the Agency will presume that you no longer want to pursue this action. The Agency will then reject your application and issue an invoice for any applicable outstanding fees.

If you have any questions, please contact the Pesticide Registration Service Fee Ombudsman at (703) 305-6249.

Sincerely,

A handwritten signature in black ink that reads "Erica Downs". The signature is written in a cursive, flowing style.

Front End Processing Staff
Information Technology & Resources Management Division

Fee for Service

{875593L~

This package includes the following

☒ New Registration

☐ Amendment

☒ Studies? ☐ Fee Waiver?

☐ volpay % Reduction: ____

for Division

☐ AD

☐ BPPD

☒ RD

Risk Mgr. 23

Receipt No.

S- 875593

EPA File Symbol/Reg. No.

87655-R

Pin-Punch Date:

5/28/2010

☐ This item is NOT subject to FFS action.

Action Code:

Requested: R-310

Granted: R-310

Amount Due: \$ 4578.00

Parent/Child Decisions:

☐ Inert Cleared for Intended Use

☐ Uncleared Inert in Product

Reviewer: Vannuzi Eagle

Date: 4/2/10

Remarks:

unregistered tech.

Receipt for Section 3



S: 875593

Regulation: ☐ Yes ☒ No

Regulatory Type: Product Registration - Section 3

Fee For Service: ☒ Yes ☐ No

Print Letter

Application Type: New Registration

Billable: ☒ Yes ☐ No

Enter More Information

Tracking

Company: 87655 ORION FOMES, LLC

V

Risk Manager: Registration Division, Risk Management Team 23

Product #: 87655-R Product Name: FOMESAFEN TECHNICAL

Override#:

Me Too
Section3: 82633-5

Me Too
Product Name: SHARDA FOMESAFEN TECHNICAL HERBICIDE

Application Date: 25-May-2010



OPP Rec'd Date: 28-May-2010



Front End Date: 01-Jun-2010



Risk Manager Send Date:



FFS Due Date:

Negotiated Due Date:

OPP Target Date:

Fast Track: ☐

New Ingredient: ☐

Receipt Description:

New registration

Receipt Content

Study

CSF

View/Edit

Form A: ☐

Signature Date

Form A: ☐

Signature Date

Robert Hawk

From: paygovadmin@mail.doc.twa.gov
Sent: Tuesday, May 25, 2010 7:36 AM
To: zaphawk@aol.com
Subject: Pay.Gov Payment Confirmation

THIS IS AN AUTOMATED MESSAGE. PLEASE DO NOT REPLY.

Your transaction has been successfully completed.

Transaction Summary

Application Name: PRIA Service Fees
Pay.gov Tracking ID: 250SD6PP
Agency Tracking ID: 74117978938

Account Holder Name: Terry K Stojic
Transaction Type: Sale
Transaction Amount: \$4,360.00
Billing Address: 7364 E Red Hawk St
City: Mesa
State/Province: AZ
Zip/Postal Code: 85207
Country: USA
Card Type: Masler Card
Card Number: *****0850
Transaction Date: May 25, 2010 10:36:19 AM

Decision Number:
Registration Number: 8570-1
Company Name: Orion Fomes, LLC
Company Number: 87655
Action Code: R310

PRIA 2 – 21 Day Content Screen Review Worksheet

(EPA/OPP Use Only)

21 Day Screen Start Date: 5-28-10 ^{3/23/09}

Experts In-Processing Signature: B.2 Date 6-4-10 Fee Paid: Yes ☒

Division management contacted on issues No ☐ Yes ☐ Date

EPA Reg. Number: <u>87655-R</u>		EPA Receipt Date: <u>5-28-10</u>				
Items for Review				Yes	No	N/A*
1	Application Form (EPA Form 8570-1)(link to form) signed & complete including package type			<input checked="" type="checkbox"/>		
2	Confidential Statement of Formula all boxes completed, form signed, and dated (EPA Form 8570-4) (Link to form)			<input checked="" type="checkbox"/>		
	a) All inerts (link to http://www.epa.gov/oppr001/inerts/), including fragrances, approved for the proposed uses (see Footnote A)	yes	no			
		<input checked="" type="checkbox"/>				
3	Certification with Respect to Citation of Data (EPA Form 8570-34) (Link to form) completed and signed (N/A if 100% repack)			<input checked="" type="checkbox"/>		
	Certificate and data matrix consistent			<input checked="" type="checkbox"/>		
	If applicant is relying on data that are compensable, is the offer to pay statement included. (see Footnote B)	yes	no			
	If applicable, is there a letter of Authorization for exclusive use only.					
4	Formulator's Exemption Statement (EPA Form 8570-27) (Link to form) completed and signed (N/A if source is unregistered or applicant owns the technical)					<input checked="" type="checkbox"/>
	Data Matrix (EPA Form 8570-35) (Link to form) both internal and external copies (PR 98-5) (Link to PR 98-5) completed and signed (N/A if 100% repack)			<input checked="" type="checkbox"/>		
5	a) Selective Method (Fee category experts use)	yes	no			
		<input checked="" type="checkbox"/>				
	b) Cite-All (Fee category experts use)					
	c) Applicant owns all data (Fee category experts use)					
6	5 Copies of Label (link to http://www.epa.gov/oppfead1/labeling/lrm/) (Electronic labels on CD are encouraged and guidance is available)(link to http://www.epa.gov/pesticides/regulating/registering/submissions/index.htm#labels)			<input checked="" type="checkbox"/>		

7	Is the data package consistent with PR Notice 86-5 (link to PRN 86-5)	X		
8	Notice of Filing (link to http://www.epa.gov/pesticides/regulating/tolerance_petitions.htm) included with petitions (link to http://www.epa.gov/pesticides/regulating/tolerances.htm)			/
9	If applicable for conventional applications, reduced risk rationale (link to http://www.epa.gov/opprd001/workplan/reducedrisk.html)			/
10	Required Data (link to http://www.epa.gov/pesticides/regulating/data_requirements.htm) and/or data waivers. See Footnote C.			
	a) List study (or studies) not included with application			

Comments:

Active and Impurities only

Passed 86-5 Review MRE 481094

-JB

481094

* N/A – Not Applicable

Footnotes

A. During the 21 day initial content review, all CSFs will be reviewed to determine whether all inerts listed, including fragrances, are approved for the proposed uses. If an unapproved inert is identified, the applicant must either 1) resolve the inert issue by, for example, removing the inert, substituting it with an approved inert, submitting documentation that EPA approved the inert for the proposed pesticidal uses, correcting mistakes on the CSF, etc. or 2) provide the data to support OPP approval of the inert or 3) withdraw the application. Removing or substituting an inert ingredient will require a new CSF and may require submission of data. All information, forms, data and documentation resolving the inert issue must have been received by the Agency or the application withdrawn within the 21 day period, otherwise, the Agency will reject the application as described below.

To successfully complete this aspect of the 21 day initial content screen, applicants are **strongly encouraged** to verify that all inert ingredients have been approved for the application's uses even if a product is currently registered by consulting the inert Web

site [link to <http://www.epa.gov/opprd001/inerts/lists.html>] and if the inert is not approved, to **obtain the necessary inert approval prior to submitting an application to register a pesticide product containing that inert ingredient**. Some inert ingredients are no longer approved for food uses or certain types of uses. The name and/or CAS number on a CSF must match the name and CAS number on this web site. Simple typographical errors in the name or CAS number have resulted in processing delays.

If an inert is not listed on the inert ingredient web site and the applicant believes that the inert has been approved, the applicant should contact the Inert Ingredient Assessment Branch (IIAB) at inertsbranch@epa.gov and resolve the issue. Copies of the correspondence with IIAB resolving the issue should accompany the application. All new inerts except PIP inerts are reviewed by IIAB. The IIAB should also be contacted for any questions on what supporting data needs to be submitted for and the Agency's inert review process. Questions on PIP inerts should be directed to the Chief of Microbial Pesticides Branch [Link to http://www.epa.gov/opbpbpd1/biopesticides/contacts_bpdpd.htm].

When a brand, trade, or proprietary name of an inert ingredient is listed on a CSF, additional information such as an alternate name of the inert, CAS number or other information [link to <http://www.epa.gov/opprd001/inerts/tips.pdf>] must also be included to enable the Agency to determine if it has been approved. Each component of an inert mixture (including a fragrance) must be identified. In some cases, the supplier of the mixture or fragrance may need to provide this information to the Agency. Prior to the Agency's receipt of an application, applicants must arrange with a proprietary mixture or fragrance supplier to provide the component information to the Agency or promptly upon EPA's request. If the inert ingredients in a proprietary blend (including fragrances) cannot or are not identified or provided within the 21-day content review period, the Agency will reject the application.

During the 21 day content review, applicants should submit information to the individual identified by the Agency when the applicant is informed of an unapproved inert.

Unapproved Inerts Identified on CSFs

All applications except conventional new products and PIPs

Once an unapproved inert is identified on a CSF, the Agency will contact the applicant with the following options:

1. Correct the application by, for instance, correcting the inert's identity or CAS number, providing documentation that the inert has been approved, or removing the unapproved inert from the CSF or replacing it with one that is approved for the application's uses; or
2. Submit the information and data needed for the Agency to approve the unapproved inert. If this option is selected and implemented, the Agency may request an extension in the PRIA decision review timeframe to accommodate the inert review/approval process;

3. Withdraw the application (the Agency retains 25% of the full fee for the fee category estimated); or

If none of these options is selected and implemented by the applicant within the 21 day content review period, the Agency will reject the application and retain 25% of the full fee of the category identified.

Conventional New Product Applications

When the Registration Division identifies an unapproved inert on a CSF with an application for a new product that the applicant has not identified as requiring an inert approval (R311, R312 or R313), it will contact the applicant with the following options:

1. Correct the application by, for instance, correcting the inert's identity or CAS number, providing documentation that the inert has been approved, or removing the unapproved inert from the CSF or replacing it with one that is approved for the application's uses; or
2. Submit the information and data needed for the Agency to approve the unapproved inert, including any required petition to establish or amend a tolerance or exemption from a tolerance. (This option may change the PRIA category for the application, which could require a longer decision review time and a larger fee. If additional fees are due, they must be received by the Agency within the 21 day content review period.)
3. Withdraw the application (the Agency retains 25% of the full fee for the fee category estimated); or

If none of the above options is selected and implemented during the 21-day content-review period, the Agency will reject the application and retain 25% of the appropriate fee for the new product-inert approval category.

PIP Applications

When the Biopesticide and Pollution Prevention Division identifies an unapproved inert on a PIP CSF and a request to approve the inert does not accompany the application, it will contact the applicant with the following options:

1. Correct the application by, for instance, correcting the spelling or name of the inert to that in 40 CFR 174, or providing documentation that the inert has been approved; or
2. Submit the information and data needed for the Agency to approve the unapproved inert. If an inert ingredient tolerance exemption petition is required, the petition must be received by the Agency and the B903 fee paid within the 21 day period. If this option is selected and implemented, the Agency will discuss harmonizing the timeframe for both actions.

3. Withdraw the application (the Agency retains 25% of the full fee for the fee category estimated); or

If none of the above options is selected and implemented during the 21 day content review period, the Agency will reject the application and retain 25% of the fee.

B. A policy on documentation of offers to pay is still being developed, however, for a me-too or fast track (similar/identical) new product, R300 or A530, an application without the necessary authorizations of offers to pay will be placed into either R301 or A531. The Agency recommends that authorizations of offers to pay be submitted with other PRIA applications to avoid delays in the Agency's decision.

C. Biopesticide applicants are advised to contact the Agency and discuss study waivers prior to submitting their application to the Agency. Documentation of such discussions should be submitted with the study waiver.

Script for Rejection Phone calls

Contact Name: Robert Hawk
Phone #: 928-942-3489
Email: zaphawk@aol.com

First Call/Initials:

Date: 6/8
Time: 1 PM

Second Call/Initials:

Date:
Time:

This is _____, EPA contractor.

I'm calling regarding your submission in support of

Application to Register - 87655-R

We have found the following deficiencies regarding:

PR Notice 86.5: Yes or No

Volume/Study Title: Vol 1 - illegible pgs 33, 39, 65, 68, 100 of CA

Volume/Study Title: Vol 3 " " pgs 6, 17

Volume/Study Title:

Additional volumes continued on back of page: Yes or No

Application Package: Yes or No

~~Data Matrix~~ should be selective method
Certification

These deficiencies have been approved by EPA.

The corrections can be faxed to 703-305-5060/Attn: _____.

Second Call/Email:

If we do not receive the corrections by _____, we will process your submission, accordingly. Please direct all future calls and correspondence to the appropriate EPA Risk Manager.



RE: Application to Register 87655-R
Robert Hawk to: Jennifer Drobish

06/10/2010 02:04 PM

Dear Ms. Drobish,

Thank you very much for your suggestion. In view of the time, I'm afraid that's what we must do. I have attached a copy of the 7 pages with "Best Available Copy" on 6 of them. For page 6 of the enforcement analytical method I have clarified that a portion of the text has been deliberately redacted. If a reviewer wishes, we can make these pages available from the PDF file that the laboratory supplied to us. Enlarging the images improves legibility, but not completely satisfactorily. We apologize for the problem.

Also please find a revised 8570-34 attached.

Again, thanks very much for your help.

Robert Hawk
tel. 928-342-3489
mobile 928-581-3895

-----Original Message-----

From: Drobish.Jennifer@epamail.epa.gov
[mailto:Drobish.Jennifer@epamail.epa.gov]
Sent: Wednesday, June 09, 2010 4:35 AM
To: Robert Hawk
Subject: RE: Application to Register 87655-R

Mr Hawk

I just wanted to let you know that this information is due on Friday [6/11/10]. I understand contacting the labs can take some time so if you are unable to get the replacement pages in time, we can accept illegible pages with "Best available copy" written or stamped on them.

Thanks
Jennifer Drobish
EPA Contractor
703-305-1671

From: "Robert Hawk" <zaphawk@aol.com>

To: Jennifer Drobish/DC/USEPA/US@EPA

Cc: Sree Nair/DC/USEPA/US@EPA

Date: 06/08/2010 02:55 PM

Subject: RE: Application to Register 87655-R

Dear Ms. Drobish,

We apologize for the legibility problems with the Product Identification and Preliminary Analysis report. It appears that I will have to contact the research lab in order to obtain clearer copies, and I will get back to you as soon as possible.

Page 6 in the Enforcement Analytical Method has a deliberate white-out of confidential information and is not problem of legibility per se (unless it did not copy properly). But p. 17 of this report is the same as p. 33 of the Preliminary Analysis report and is a problem.

I will send you a revised Certification (8570-34) when I send you replacement pages for the reports.

Again my apologies. Regards.

Robert Hawk
tel. 928-342-3489
mobile 928-581-3895

-----Original Message-----

From: Drobish.Jennifer@epamail.epa.gov
[mailto:Drobish.Jennifer@epamail.epa.gov]
Sent: Tuesday, June 08, 2010 10:08 AM
To: zaphawk@aol.com
Cc: nair.sree@epa.gov
Subject: Application to Register 87655-R

Mr Hawk

This is Jennifer Drobish, EPA contractor. I'm writing to you in regards to your submission in support of the application for registration of the above product. I attempted to call, but I may have the wrong number. We have found the following deficiencies regarding PR Notice 86.5 and the Application Package:

PR Notice 86.5:

- "Fomesafen Technical: Product Identification and Preliminary Analysis": the following pages of the confidential attachment are illegible: pgs. 33, 39, 65, 68, 100.

- "Fomesafen Technical: Enforcement Analytical Method": the following pages are illegible: pgs. 6, 17.

Application Package:

- the Certification with Respect to Citation of Data (EPA form 8570-34) is inconsistent with the Data Matrix. Please select the "Selective method" on the Certification, there is a "cite-all" option under the selective method.

This information can either be faxed to me at 703-305-5060/Attn: Jennifer Drobish or emailed to me at drobish.jennifer@epa.gov

If you have any questions please feel free to contact me.

Thank you
Jennifer Drobish
EPA Contractor
703-305-1671



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

June 11, 2010

OFFICE OF
PREVENTION, PESTICIDES AND
TOXIC SUBSTANCES

ORION FOMES, LLC
PO Box 21720
MESA, AZ 85277-

Report of Analysis for Compliance with PR Notice 86-5

Thank you for your submittal of 28-MAY-10. Our staff has completed a preliminary analysis of the material. The results are provided as follows:

Your submittal was found to be in full compliance with the standards for submission of data contained in PR Notice 86-5. A copy of your bibliography is enclosed, annotated with Master Record ID's (MRIDs) assigned to each document submitted. Please use these numbers in all future references to these documents. Thank you for your cooperation. If you have any questions concerning this data submission, please raise them with the cognizant Product Manager, to whom the data have been released.

draft Orion Fomes Fomesafen label May 25, 2010

FOMESAFEN TECHNICAL

FOR FORMULATING USE ONLY

ACTIVE INGREDIENT

Fomesafen [5-[2-chloro-4-(trifluoromethyl)phenoxy]-N-(methylsulfonyl)-2-nitrobenzamide].....98.0%

OTHER INGREDIENTS:.....2.0%**TOTAL**.....100.0%

KEEP OUT OF REACH OF CHILDREN

DANGER/PELOGRO

Si usted no entiende la etiqueta, busque a alguien para que se la explique a usted en detalle.
(If you do not understand the label, find someone to explain it to you in detail.)

See Additional Precautionary Statements and Directions for Use on label.

FIRST AID

IF IN EYES	<ul style="list-style-type: none"> • Hold eye open and rinse slowly and gently with water for 15-20 minutes. • Remove contact lenses, if present, after the first 5 minutes, then continue rinsing eye. • Call a poison control center or doctor for treatment advice.
IF SWALLOWED	<ul style="list-style-type: none"> • Call a poison control center or doctor immediately for treatment advice. • Have person sip a glass of water if able to swallow. • Do not induce vomiting unless told to do so by a poison control center or doctor. • Do not give anything by mouth to an unconscious person.
IF ON SKIN OR CLOTHING	<ul style="list-style-type: none"> • Take off contaminated clothing. • Rinse skin immediately with plenty of water for 15-20 minutes. • Call a poison control center or doctor for treatment advice.
IF INHALED	<ul style="list-style-type: none"> • Move person to fresh air. • If person is not breathing, call 911 or an ambulance, then give artificial respiration, preferably by mouth-to-mouth if possible. • Call a poison control center or doctor for further treatment advice.

For **MEDICAL** Emergencies 24 Hours a Day Call a Poison Control Center at 1-800-222-1222.
For **CHEMICAL** Emergency Assistance (Spill, Fire or Accident) Call ChemTree at 1-800-424-9300
Have the product container or label with you when calling a Poison Control Center or doctor or going for treatment.

NOTE TO PHYSICIAN

Probable mucosal damage may contraindicate the use of gastric lavage.

Orion Fomes, LLC
P.O. Box 21720
Mesa, AZ 85277

EPA Reg. No. 87655-x
EPA Est. No. xxxxxxxx
Net Contents: 20 kg

Tel. 480-218-4289

PRECAUTIONARY STATEMENTS

HAZARDS TO HUMANS AND DOMESTIC ANIMALS

CORROSIVE. CAUSES IRREVERSIBLE EYE DAMAGE. DUE TO CORROSIVE NATURE, MAY BE HARMFUL OR FATAL IF SWALLOWED. HARMFUL IF INHALED OR ABSORBED THROUGH SKIN. Do not get in eyes, on skin or on clothing. Avoid breathing vapor.

PERSONAL PROTECTIVE EQUIPMENT (PPE)

Manufacturers and other handlers must wear:

- Coveralls
- Waterproof gloves
- Shoes plus socks
- Protective eyewear

Discard clothing and other absorbent materials that have been heavily contaminated with this technical material. Do not reuse them.

USER SAFETY RECOMMENDATIONS

Users should:

- Wash thoroughly with soap and water after handling and before eating, drinking, chewing gum, using tobacco or using the toilet.
- Remove clothing immediately if pesticide gets inside. Then wash thoroughly and put on clean clothing.
- Remove PPE immediately after handling this product. Wash the outside of gloves before removing. As soon as possible, wash thoroughly and change into clean clothing.

ENVIRONMENTAL HAZARDS

Do not discharge effluent containing this product into lakes, streams, ponds, estuaries, oceans or other waters unless in accordance with the requirements of a National Pollutant Discharge Elimination System (NPDES) permit and the permitting authority has been notified in writing prior to discharge. Do not discharge effluent containing this product to sewer systems without previously notifying the local sewage treatment plant authority. For guidance contact your State Water Board or Regional Office of the EPA.

DIRECTIONS FOR USE

It is a violation of federal law to use this product in a manner inconsistent with its labeling.

Formulators using this product are responsible for obtaining EPA registration for their formulated products.

Fomesafen Technical is intended solely for the formulation into herbicide products intended for the following uses:

Terrestrial Food Use: Soybeans

Uses for which the USEPA has accepted the required data and/or citations of data that the formulator has submitted in support of registration, and uses for experimental purposes that are in compliance with USEPA requirements.

STORAGE AND DISPOSAL

Do not contaminate water, food, or feed by storage, disposal, or cleaning of equipment.

PESTICIDE STORAGE: Store above 32°F in original container only. Keep container closed when not in use. Do not store near food or feed. In case of spill on floor or paved surfaces, sweep up and remove to chemical waste area.

PESTICIDE DISPOSAL: Pesticide wastes are acutely toxic. Improper disposal of excess pesticide, spray mixture, or rinsate is a violation of Federal law. If these wastes cannot be disposed of by use according to label instructions, contact your State Pesticide or Environmental Control Agency or the Hazardous Waste representative at the nearest EPA Regional Office for guidance.

CONTAINER DISPOSAL: Nonrefillable container. Do not reuse empty container.

Triple rinse as follows: Empty the remaining contents into application equipment or a mix tank. Fill the container ¼ full with water. Replace and tighten closures. Tip container on its side and roll it back and forth, ensuring at least one complete revolution, for 30 seconds. Stand the container on its end and tip it back and forth several times. Empty the rinsate into the application equipment or a mix tank to store rinsate for later use or disposal. Drain for 10 seconds after the flow begins to drip. Repeat this procedure two more times.

Pressure rinse as follows: Empty the remaining contents into application or a mix tank. Hold container upside down over mix tank or collect rinsate for later use or disposal. Insert pressure rinsing nozzle in the side of the container and rinse at about 40 PSI for at least 30 seconds. Drain for 10 seconds after the flow begins to drip.

DISCLAIMER OF WARRANTIES: TO THE EXTENT CONSISTENT WITH APPLICABLE LAW, ORION FOMES LLC MAKES NO OTHER WARRANTIES, EXPRESS OR IMPLIED, OF MERCHANTABILITY OR OF FITNESS FOR A PARTICULAR PURPOSE OR OTHERWISE, THAT EXTEND BEYOND THE STATEMENTS MADE ON THIS LABEL. No agent of Orion Fomes LLC is authorized to make any warranties beyond those contained herein or to modify the warranties contained herein.

TO THE EXTENT CONSISTENT WITH APPLICABLE LAW, ORION FOMES LLC DISCLAIMS ANY LIABILITY WHATSOEVER FOR SPECIAL, INCIDENTAL OR CONSEQUENTIAL DAMAGES RESULTING FROM THE USE OR HANDLING OF THIS PRODUCT.

LIMITATIONS OF LIABILITY: TO THE EXTENT CONSISTENT WITH APPLICABLE LAW, THE EXCLUSIVE REMEDY OF THE USER OR BUYER FOR ANY AND ALL LOSSES, INJURIES OR DAMAGES RESULTING FROM THE USE OR HANDLING OF THIS PRODUCT, WHETHER IN CONTRACT, WARRANTY, TORT, NEGLIGENCE, STRICT LIABILITY OR OTHERWISE, SHALL NOT EXCEED THE PURCHASE PRICE PAID, OR AT ORION FOMES LLC'S ELECTION, THE REPLACEMENT OF PRODUCT.

draft Orion Fomes Fomesafen label May 25, 2016

FOMESAFEN PRELIMINARY

FOR FORMULATING USE ONLY

ACTIVE INGREDIENT

Fomesafen [5-[2-chloro-4-trifluoromethyl)phenoxy]-N-(methylsulfonyl)-2-nitrobenzamide].....98.0%

OTHER INGREDIENTS:.....2.0%**TOTAL**..... 100.0%

KEEP OUT OF REACH OF CHILDREN

DANGER/PELOGRO

Si usted no entiende la etiqueta, busque a alguien para que se la explique a usted en detalle.
(If you do not understand the label, find someone to explain it to you in detail.)

See Additional Precautionary Statements and Directions for Use on label.

FIRST AID

IF IN EYES	<ul style="list-style-type: none"> • Hold eye open and rinse slowly and gently with water for 15-20 minutes. • Remove contact lenses, if present, after the first 5 minutes, then continue rinsing eye. • Call a poison control center or doctor for treatment advice.
IF SWALLOWED	<ul style="list-style-type: none"> • Call a poison control center or doctor immediately for treatment advice. • Have person sip a glass of water if able to swallow. • Do not induce vomiting unless told to do so by a poison control center or doctor. • Do not give anything by mouth to an unconscious person.
IF ON SKIN OR CLOTHING	<ul style="list-style-type: none"> • Take off contaminated clothing. • Rinse skin immediately with plenty of water for 15-20 minutes. • Call a poison control center or doctor for treatment advice.
IF INHALED	<ul style="list-style-type: none"> • Move person to fresh air. • If person is not breathing, call 911 or an ambulance, then give artificial respiration, preferably by mouth-to-mouth if possible. • Call a poison control center or doctor for further treatment advice.

For MEDICAL Emergencies 24 Hours a Day Call a Poison Control Center at 1-800-222-1222.
For CHEMICAL Emergency Assistance (Spill, Fire or Accident) Call ChemTrec at 1-800-424-9300
Have the product container or label with you when calling a Poison Control Center or doctor or going for treatment.

NOTE TO PHYSICIAN

Probable mucosal damage may contraindicate the use of gastric lavage.

Orion Fomes, LLC
P.O. Box 21720
Mesa, AZ 85277

EPA Reg. No. 87655-x
EPA Est. No. xxxxxxxx
Net Contents: 30 kg

Tel. 480-218-4289

PRECAUTIONARY STATEMENTS

HAZARDS TO HUMANS AND DOMESTIC ANIMALS

CORROSIVE. CAUSES IRREVERSIBLE EYE DAMAGE. DUE TO CORROSIVE NATURE, MAY BE HARMFUL OR FATAL IF SWALLOWED. HARMFUL IF INHALED OR ABSORBED THROUGH SKIN. Do not get in eyes, on skin or on clothing. Avoid breathing vapor.

PERSONAL PROTECTIVE EQUIPMENT (PPE)

Manufacturers and other handlers must wear:

- Coveralls
- Waterproof gloves
- Shoes plus socks
- Protective eyewear

Discard clothing and other absorbent materials that have been heavily contaminated with this technical material. Do not reuse them.

USER SAFETY RECOMMENDATIONS

Users should:

- Wash thoroughly with soap and water after handling and before eating, drinking, chewing gum, using tobacco or using the toilet.
- Remove clothing immediately if pesticide gets inside. Then wash thoroughly and put on clean clothing.
- Remove PPE immediately after handling this product. Wash the outside of gloves before removing. As soon as possible, wash thoroughly and change into clean clothing.

ENVIRONMENTAL HAZARDS

Do not discharge effluent containing this product into lakes, streams, ponds, estuaries, oceans or other waters unless in accordance with the requirements of a National Pollutant Discharge Elimination System (NPDES) permit and the permitting authority has been notified in writing prior to discharge. Do not discharge effluent containing this product to sewer systems without previously notifying the local sewage treatment plant authority. For guidance contact your State Water Board or Regional Office of the EPA.

DIRECTIONS FOR USE

It is a violation of federal law to use this product in a manner inconsistent with its labeling.

Formulators using this product are responsible for obtaining EPA registration for their formulated products

Fomesafen Technical is intended solely for the formulation into herbicide products intended for the following uses:

Terrestrial Food Use: Soybeans

Uses for which the USEPA has accepted the required data and/or citations of data that the formulator has submitted in support of registration, and uses for experimental purposes that are in compliance with USEPA requirements.

STORAGE AND DISPOSAL

Do not contaminate water, food, or feed by storage, disposal, or cleaning of equipment.

PESTICIDE STORAGE: Store above 32°F in original container only. Keep container closed when not in use. Do not store near food or feed. In case of spill on floor or paved surfaces, sweep up and remove to chemical waste area.

PESTICIDE DISPOSAL: Pesticide wastes are acutely toxic. Improper disposal of excess pesticide, spray mixture, or rinsate is a violation of Federal law. If these wastes cannot be disposed of by use according to label instructions, contact your State Pesticide or Environmental Control Agency or the Hazardous Waste representative at the nearest EPA Regional Office for guidance.

CONTAINER DISPOSAL: Nonrefillable container. Do not reuse empty container.

Triple rinse as follows: Empty the remaining contents into application equipment or a mix tank. Fill the container ¼ full with water. Replace and tighten closures. Tip container on its side and roll it back and forth, ensuring at least one complete revolution, for 30 seconds. Stand the container on its end and tip it back and forth several times. Empty the rinsate into the application equipment or a mix tank to store rinsate for later use or disposal. Drain for 10 seconds after the flow begins to drip. Repeat this procedure two more times.

Pressure rinse as follows: Empty the remaining contents into application or a mix tank. Hold container upside down over mix tank or collect rinsate for later use or disposal. Insert pressure rinsing nozzle in the side of the container and rinse at about 40 PSI for at least 30 seconds. Drain for 10 seconds after the flow begins to drip.

DISCLAIMER OF WARRANTIES: TO THE EXTENT CONSISTENT WITH APPLICABLE LAW, ORION FOMES LLC MAKES NO OTHER WARRANTIES, EXPRESS OR IMPLIED, OF MERCHANTABILITY OR OF FITNESS FOR A PARTICULAR PURPOSE OR OTHERWISE, THAT EXTEND BEYOND THE STATEMENTS MADE ON THIS LABEL. No agent of Orion Fomes LLC is authorized to make any warranties beyond those contained herein or to modify the warranties contained herein.

TO THE EXTENT CONSISTENT WITH APPLICABLE LAW, ORION FOMES LLC DISCLAIMS ANY LIABILITY WHATSOEVER FOR SPECIAL, INCIDENTAL OR CONSEQUENTIAL DAMAGES RESULTING FROM THE USE OR HANDLING OF THIS PRODUCT.

LIMITATIONS OF LIABILITY: TO THE EXTENT CONSISTENT WITH APPLICABLE LAW, THE EXCLUSIVE REMEDY OF THE USER OR BUYER FOR ANY AND ALL LOSSES, INJURIES OR DAMAGES RESULTING FROM THE USE OR HANDLING OF THIS PRODUCT, WHETHER IN CONTRACT, WARRANTY, TORT, NEGLIGENCE, STRICT LIABILITY OR OTHERWISE, SHALL NOT EXCEED THE PURCHASE PRICE PAID, OR AT ORION FOMES LLC'S ELECTION, THE REPLACEMENT OF PRODUCT.

draft Orion Fomes Fomesafen label May 25, 2010

FOMESAFEN TECHNICAL

FOR FORMULATING USE ONLY

ACTIVE INGREDIENT

Fomesafen [5-[2-chloro-4-(trifluoromethyl)phenoxy]-N-(methylsulfonyl)-2-nitrobenzamide].....98.0%

OTHER INGREDIENTS:.....2.0%**TOTAL**..... 100.0%

KEEP OUT OF REACH OF CHILDREN

DANGER/PELOGRO

Si usted no entiende la etiqueta, busque a alguien para que se la explique a usted en detalle.

(If you do not understand the label, find someone to explain it to you in detail.)

See Additional Precautionary Statements and Directions for Use on label.

FIRST AID

IF IN EYES	<ul style="list-style-type: none"> • Hold eye open and rinse slowly and gently with water for 15-20 minutes. • Remove contact lenses, if present, after the first 5 minutes, then continue rinsing eye. • Call a poison control center or doctor for treatment advice.
IF SWALLOWED	<ul style="list-style-type: none"> • Call a poison control center or doctor immediately for treatment advice. • Have person sip a glass of water if able to swallow. • Do not induce vomiting unless told to do so by a poison control center or doctor. • Do not give anything by mouth to an unconscious person.
IF ON SKIN OR CLOTHING	<ul style="list-style-type: none"> • Take off contaminated clothing. • Rinse skin immediately with plenty of water for 15-20 minutes. • Call a poison control center or doctor for treatment advice.
IF INHALED	<ul style="list-style-type: none"> • Move person to fresh air. • If person is not breathing, call 911 or an ambulance, then give artificial respiration, preferably by mouth-to-mouth if possible. • Call a poison control center or doctor for further treatment advice.
For MEDICAL Emergencies 24 Hours a Day Call a Poison Control Center at 1-800-222-1222. For CHEMICAL Emergency Assistance (Spill, Fire or Accident) Call ChemTrec at 1-800-424-9300 Have the product container or label with you when calling a Poison Control Center or doctor or going for treatment.	
NOTE TO PHYSICIAN	
Probable mucosal damage may contraindicate the use of gastric lavage.	

Orion Fomes, LLC
P.O. Box 21720
Mesa, AZ 85277

EPA Reg. No. 87655-x
EPA Est. No. xxxxxxxx
Net Contents: 30 kg

Tel. 480-218-4289

PRECAUTIONARY STATEMENTS

HAZARDS TO HUMANS AND DOMESTIC ANIMALS

CORROSIVE. CAUSES IRREVERSIBLE EYE DAMAGE. DUE TO CORROSIVE NATURE, MAY BE HARMFUL OR FATAL IF SWALLOWED. HARMFUL IF INHALED OR ABSORBED THROUGH SKIN. Do not get in eyes, on skin or on clothing. Avoid breathing vapor.

PERSONAL PROTECTIVE EQUIPMENT (PPE)

Manufacturers and other handlers must wear:

- Coveralls
- Waterproof gloves
- Shoes plus socks
- Protective eyewear

Discard clothing and other absorbent materials that have been heavily contaminated with this technical material. Do not reuse them.

USER SAFETY RECOMMENDATIONS

Users should:

- Wash thoroughly with soap and water after handling and before eating, drinking, chewing gum, using tobacco or using the toilet.
- Remove clothing immediately if pesticide gets inside. Then wash thoroughly and put on clean clothing.
- Remove PPE immediately after handling this product. Wash the outside of gloves before removing. As soon as possible, wash thoroughly and change into clean clothing.

ENVIRONMENTAL HAZARDS

Do not discharge effluent containing this product into lakes, streams, ponds, estuaries, oceans or other waters unless in accordance with the requirements of a National Pollutant Discharge Elimination System (NDPES) permit and the permitting authority has been notified in writing prior to discharge. Do not discharge effluent containing this product to sewer systems without previously notifying the local sewage treatment plant authority. For guidance contact your State Water Board or Regional Office of the EPA.

DIRECTIONS FOR USE

It is a violation of federal law to use this product in a manner inconsistent with its labeling.

Formulators using this product are responsible for obtaining EPA registration for their formulated products.

Fomesafen Technical is intended solely for the formulation into herbicide products intended for the following uses:

Terrestrial Food Use: Soybeans

Uses for which the USEPA has accepted the required data and/or citations of data that the formulator has submitted in support of registration, and uses for experimental purposes that are in compliance with USEPA requirements.

STORAGE AND DISPOSAL

Do not contaminate water, food, or feed by storage, disposal, or cleaning of equipment.

PESTICIDE STORAGE: Store above 32°F in original container only. Keep container closed when not in use. Do not store near food or feed. In case of spill on floor or paved surfaces, sweep up and remove to chemical waste area.

PESTICIDE DISPOSAL: Pesticide wastes are acutely toxic. Improper disposal of excess pesticide, spray mixture, or rinsate is a violation of Federal law. If these wastes cannot be disposed of by use according to label instructions, contact your State Pesticide or Environmental Control Agency or the Hazardous Waste representative at the nearest EPA Regional Office for guidance.

CONTAINER DISPOSAL: Nonrefillable container. Do not reuse empty container.

Triple rinse as follows: Empty the remaining contents into application equipment or a mix tank. Fill the container ¼ full with water. Replace and tighten closures. Tip container on its side and roll it back and forth, ensuring at least one complete revolution, for 30 seconds. Stand the container on its end and tip it back and forth several times. Empty the rinsate into the application equipment or a mix tank to store rinsate for later use or disposal. Drain for 10 seconds after the flow begins to drip. Repeat this procedure two more times.

Pressure rinse as follows: Empty the remaining contents into application or a mix tank. Hold container upside down over mix tank or collect rinsate for later use or disposal. Insert pressure rinsing nozzle in the side of the container and rinse at about 40 PSI for at least 30 seconds. Drain for 10 seconds after the flow begins to drip.

DISCLAIMER OF WARRANTIES: TO THE EXTENT CONSISTENT WITH APPLICABLE LAW, ORION FOMES LLC MAKES NO OTHER WARRANTIES, EXPRESS OR IMPLIED, OF MERCHANTABILITY OR OF FITNESS FOR A PARTICULAR PURPOSE OR OTHERWISE, THAT EXTEND BEYOND THE STATEMENTS MADE ON THIS LABEL. No agent of Orion Fomes LLC is authorized to make any warranties beyond those contained herein or to modify the warranties contained herein.

TO THE EXTENT CONSISTENT WITH APPLICABLE LAW, ORION FOMES LLC DISCLAIMS ANY LIABILITY WHATSOEVER FOR SPECIAL, INCIDENTAL OR CONSEQUENTIAL DAMAGES RESULTING FROM THE USE OR HANDLING OF THIS PRODUCT.

LIMITATIONS OF LIABILITY: TO THE EXTENT CONSISTENT WITH APPLICABLE LAW, THE EXCLUSIVE REMEDY OF THE USER OR BUYER FOR ANY AND ALL LOSSES, INJURIES OR DAMAGES RESULTING FROM THE USE OR HANDLING OF THIS PRODUCT, WHETHER IN CONTRACT, WARRANTY, TORT, NEGLIGENCE, STRICT LIABILITY OR OTHERWISE, SHALL NOT EXCEED THE PURCHASE PRICE PAID, OR AT ORION FOMES LLC'S ELECTION, THE REPLACEMENT OF PRODUCT.

draft Orion Fomes Fomesafen label May 25, 2010

FOMESAFEN TECHNICAL

FOR FORMULATING USE ONLY

ACTIVE INGREDIENT

Fomesafen [5-[2-chloro-4-(trifluoromethyl)phenoxy]-N-(methylsulfonyl)-2-nitrobenzamide].....98.0%

OTHER INGREDIENTS:.....2.0%**TOTAL**.....100.0%

KEEP OUT OF REACH OF CHILDREN

DANGER/PELOGRO

Si usted no entiende la etiqueta, busque a alguien para que se la explique a usted en detalle.
(If you do not understand the label, find someone to explain it to you in detail.)

See Additional Precautionary Statements and Directions for Use on label.

FIRST AID

IF IN EYES	<ul style="list-style-type: none"> Hold eye open and rinse slowly and gently with water for 15-20 minutes. Remove contact lenses, if present, after the first 5 minutes, then continue rinsing eye. Call a poison control center or doctor for treatment advice.
IF SWALLOWED	<ul style="list-style-type: none"> Call a poison control center or doctor immediately for treatment advice. Have person sip a glass of water if able to swallow. Do not induce vomiting unless told to do so by a poison control center or doctor. Do not give anything by mouth to an unconscious person.
IF ON SKIN OR CLOTHING	<ul style="list-style-type: none"> Take off contaminated clothing. Rinse skin immediately with plenty of water for 15-20 minutes. Call a poison control center or doctor for treatment advice.
IF INHALED	<ul style="list-style-type: none"> Move person to fresh air. If person is not breathing, call 911 or an ambulance, then give artificial respiration, preferably by mouth-to-mouth if possible. Call a poison control center or doctor for further treatment advice.

For MEDICAL Emergencies 24 Hours a Day Call a Poison Control Center at 1-800-222-1222.
For CHEMICAL Emergency Assistance (Spill, Fire or Accident) Call ChemTrec at 1-800-424-9300
Have the product container or label with you when calling a Poison Control Center or doctor or going for treatment.

NOTE TO PHYSICIAN

Probable mucosal damage may contraindicate the use of gastric lavage.

Orion Fomes, LLC
P.O. Box 21720
Mesa, AZ 85277

EPA Reg. No. 87655-x
EPA Est. No. XXXXX
Net Contents: 30 kg

Tel. 480-218-4289

PRECAUTIONARY STATEMENTS

HAZARDS TO HUMANS AND DOMESTIC ANIMALS

CORROSIVE. CAUSES IRREVERSIBLE EYE DAMAGE. DUE TO CORROSIVE NATURE, MAY BE HARMFUL OR FATAL IF SWALLOWED. HARMFUL IF INHALED OR ABSORBED THROUGH SKIN. Do not get in eyes, on skin or on clothing. Avoid breathing vapor.

PERSONAL PROTECTIVE EQUIPMENT (PPE)

Manufacturers and other handlers must wear:

- Coveralls
- Waterproof gloves
- Shoes plus socks
- Protective eyewear

Discard clothing and other absorbent materials that have been heavily contaminated with this technical material. Do not reuse them.

USER SAFETY RECOMMENDATIONS

Users should:

- Wash thoroughly with soap and water after handling and before eating, drinking, chewing gum, using tobacco or using the toilet.
- Remove clothing immediately if pesticide gets inside. Then wash thoroughly and put on clean clothing.
- Remove PPE immediately after handling this product. Wash the outside of gloves before removing. As soon as possible, wash thoroughly and change into clean clothing.

ENVIRONMENTAL HAZARDS

Do not discharge effluent containing this product into lakes, streams, ponds, estuaries, oceans or other waters unless in accordance with the requirements of a National Pollutant Discharge Elimination System (NDPES) permit and the permitting authority has been notified in writing prior to discharge. Do not discharge effluent containing this product to sewer systems without previously notifying the local sewage treatment plant authority. For guidance contact your State Water Board or Regional Office of the EPA.

DIRECTIONS FOR USE

It is a violation of federal law to use this product in a manner inconsistent with its labeling.

Formulators using this product are responsible for obtaining EPA registration for their formulated products.

Fomesafen Technical is intended solely for the formulation into herbicide products intended for the following uses:

Terrestrial Food Use: Soybeans

Uses for which the USEPA has accepted the required data and/or citations of data that the formulator has submitted in support of registration, and uses for experimental purposes that are in compliance with USEPA requirements.

STORAGE AND DISPOSAL

Do not contaminate water, food, or feed by storage, disposal, or cleaning of equipment.

PESTICIDE STORAGE: Store above 32°F in original container only. Keep container closed when not in use. Do not store near food or feed. In case of spill on floor or paved surfaces, sweep up and remove to chemical waste area.

PESTICIDE DISPOSAL: Pesticide wastes are acutely toxic. Improper disposal of excess pesticide, spray mixture, or rinsate is a violation of Federal law. If these wastes cannot be disposed of by use according to label instructions, contact your State Pesticide or Environmental Control Agency or the Hazardous Waste representative at the nearest EPA Regional Office for guidance.

CONTAINER DISPOSAL: Nonrefillable container. Do not reuse empty container.

Triple rinse as follows: Empty the remaining contents into application equipment or a mix tank. Fill the container ¼ full with water. Replace and tighten closures. Tip container on its side and roll it back and forth, ensuring at least one complete revolution, for 30 seconds. Stand the container on its end and tip it back and forth several times. Empty the rinsate into the application equipment or a mix tank to store rinsate for later use or disposal. Drain for 10 seconds after the flow begins to drip. Repeat this procedure two more times.

Pressure rinse as follows: Empty the remaining contents into application or a mix tank. Hold container upside down over mix tank or collect rinsate for later use or disposal. Insert pressure rinsing nozzle in the side of the container and rinse at about 40 PSI for at least 30 seconds. Drain for 10 seconds after the flow begins to drip.

DISCLAIMER OF WARRANTIES: TO THE EXTENT CONSISTENT WITH APPLICABLE LAW, ORION FOMES LLC MAKES NO OTHER WARRANTIES, EXPRESS OR IMPLIED, OF MERCHANTABILITY OR OF FITNESS FOR A PARTICULAR PURPOSE OR OTHERWISE, THAT EXTEND BEYOND THE STATEMENTS MADE ON THIS LABEL. No agent of Orion Fomes LLC is authorized to make any warranties beyond those contained herein or to modify the warranties contained herein.

TO THE EXTENT CONSISTENT WITH APPLICABLE LAW, ORION FOMES LLC DISCLAIMS ANY LIABILITY WHATSOEVER FOR SPECIAL, INCIDENTAL OR CONSEQUENTIAL DAMAGES RESULTING FROM THE USE OR HANDLING OF THIS PRODUCT.

LIMITATIONS OF LIABILITY: TO THE EXTENT CONSISTENT WITH APPLICABLE LAW, THE EXCLUSIVE REMEDY OF THE USER OR BUYER FOR ANY AND ALL LOSSES, INJURIES OR DAMAGES RESULTING FROM THE USE OR HANDLING OF THIS PRODUCT, WHETHER IN CONTRACT, WARRANTY, TORT, NEGLIGENCE, STRICT LIABILITY OR OTHERWISE, SHALL NOT EXCEED THE PURCHASE PRICE PAID, OR AT ORION FOMES LLC'S ELECTION, THE REPLACEMENT OF PRODUCT.

Pages 93-99 *Confidential Statements of Formula may be entitled to confidential treatment*

Fomesafen Technical: 87655-R
Robert Hawk
to:
Shyam Mathur
11/10/2010 01:19 PM
[Show Details](#)

Dear Dr. Mathur,

Thank you very much for your telephone call. A corrected Confidential Statement of Formula is attached.

As we discussed, the 5-batch analysis would allow a claim of greater than 98.0% purity. However, Orion Fomes, LLC has deliberately chosen a somewhat lower number due to a consideration of enforcement analysis. Every enforcement analysis has some degree of error associated with it. If the label claim exactly matched the 5-batch analysis and if an enforcement analysis were erroneously low, this could result in unnecessary regulatory difficulties. However, the probability of such a problem occurring is lower if the label claim is slightly lower than what the 5-batch analysis would allow.

Regards,

Robert Hawk
Agent, Orion Fomes, LLC